EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	53009	"705"/$.ccls.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:05
S2	168	central near3 manager near3 database	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:06
S3	136188	portal or gateway	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:07
S4	9191	medical and education	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:07
S5	1267837	diagnosis or analysis	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:07
S6	12147	implantable adj medical adj device	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:08
S7	1293	(diagnostic or medical) adj codes	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:08

EAST Search History

S8	38174	(diagnostic or medical) adj treatment	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:09
S9	456	(remote or distant) near5 medical near5 (treatment or evaluation)	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:09
S10	579	electronic near3 prescriptions	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:10
S11	12351455	(disease education) or (medical device education) or (general medical information) or (diet information) or (exercise information) or (clinical resource information)	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:17
S12	1147	electronic adj medical adj record	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:18
S13	27	S1 and S2	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 15:07
S14	63	S2 and S3	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:20

EAST Search History

S15	1	S14 and S4	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:20
S16	6017	S4 and S5	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:21
S17	1013	S16 and S1	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:21
S18	1	S17 and S2	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 15:07
S19	10	S17 and S6	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:21
S20	30	S17 and S7	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:56
S21	205	S17 and S8	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:22

S22	5	S9 and S21	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:56
S23	32	S17 and S10	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:41
S24	51490	S11 and S1	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:23
S25	500	S1 and S12	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:24
S26	5	S22 and S24	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:40
S27	4	S22 and S25	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2007/08/29 14:24

Rapillo, Kristine K.

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Documents

- **eDoc sees black ink, deal with UA system**
  Mark Friedman. **Northwest Arkansas Business Journal**. Fayetteville:Aug 4, 2003. Vol. 7, Iss. 10, p. 20

- **Arkansas Regulators Crack Down on Internet-Based Medical Services Firm**
  Jake Bleed. **Knight Ridder Tribune Business News**. Washington:Mar 22, 2002. p. 1

Citation style: ProQuest Standard

Document 1 of 2

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Abstract (Summary)
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Indexing (document details)

Subjects:	Online information services, Colleges & universities, Contracts, Revenue, Financial performance
Classification Codes	9190, 3100, 8331, 8306
Locations:	Little Rock Arkansas
Companies:	eDocAmerica.com (**NAICS:** 519190) , University of Arkansas System (**NAICS:** 611310)
Author(s):	Mark Friedman

Document types:	News
Section:	*Focus: Health care technology*
Publication title:	Northwest Arkansas Business Journal. Fayetteville: Aug 4, 2003. Vol. 7, Iss. 10; pg. 20
Source type:	Periodical
ProQuest document ID:	391432931
Text Word Count	1203
Document URL:	http://proquest.umi.com/pqdweb?did=391432931&Fmt=4&clientId=19649&RQT=309&VName=PQD

Document 2 of 2

Arkansas Regulators Crack Down on Internet-Based Medical Services Firm

Jake Bleed. **Knight Ridder Tribune Business News.** Washington:Mar 22, 2002. p. 1

Abstract (Summary)
Regulators say doctors should only offer prescriptions after meeting a patient face to face and gain a firsthand understanding of the patient's problem and history. Regulators add that offering prescriptions over the Internet is a risky business that leaves physicians at the mercy of patients, who may lie to get the drugs they want.

Robbie Linn, president of MD Online, stresses that online prescriptions are a very small part of his business -- eDocAmerica still fills prescriptions from outside Arkansas -- and that the company is happy to cooperate with regulators.

They then fill out an online questionnaire similar to those handed out in actual doctors offices that give physicians the information they need to give basic health advice, Linn said. Correspondence between patient and physician takes place over a secure Internet connection on the eDocAmerica Web site. If the eDocAmerica physician does grant a prescription, he faxes it to the pharmacy of the patient's choice.

Indexing (document details)

People:	Linn, Robbie
Companies:	MD Online LLC
Author(s):	Jake Bleed
Publication title:	Knight Ridder Tribune Business News. Washington: Mar 22, 2002. pg. 1
Source type:	Wire Feed
ProQuest document ID:	110893932
Text Word Count	757
Document URL:	http://proquest.umi.com/pqdweb?did=110893932&Fmt=3&clientId=19649&RQT=309&VName=PQD

Rapillo, Kristine K.

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Sent: Wednesday, September 05, 2007 9:13 AM
To: Rapillo, Kristine K.
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- **The internet**
  R Al-Shahi, M Sadler, G Rees, D Bateman. **Journal of Neurology, Neurosurgery and Psychiatry**. London:Dec 2002. Vol. 73, Iss. 6, p. 619-28

- **E-healthcare: A vehicle of change**
  Binshan Lin, Daniel Umoh. **American Business Review**. West Haven:Jun 2002. Vol. 20, Iss. 2, p. 27-32 (6 pp.)

- **Building and Implementing Physician Practice Web Sites**
  Robert R Orford. **Mayo Clinic Proceedings**. Rochester:Feb 2002. Vol. 77, Iss. 2, p. 206 (1 pp.)

Allowing FDA regulation of communications software used in telemedicine: A potentially fatal misdiagnosis?
Ann K Schooley. **Federal Communications Law Journal.** Los Angeles:May 1998. Vol. 50, Iss. 3, p. 731-751 (21 pp.)

Home is where the heart monitor is
Carol Lewis. **FDA Consumer.** Rockville:May/Jun 2001. Vol. 35, Iss. 3, p. 10-5 (5 pp.)

Online Heart Exams for Veterans:[FINAL Edition]
Leslie Walker. **The Washington Post.** Washington, D.C.:May 18, 2003. p. F.07

New dimensions open up for patients and doctors HEALTH AND MEDICINE by Nuala Moran The internet will transform medical diagnosis and healthcare, while patients will gain access to far more information about their illnesses and possible treatments:[Surveys edition]
Moran, Nuala. **Financial Times.** London (UK):Dec 1, 1999. p. 04

Telemedicine: An emerging health care technology
Mary B Myers. **The Health Care Manager.** Frederick:Jul-Sep 2003. Vol. 22, Iss. 3, p. 219-223

Telemedicine; New Internet protocol used successfully for ultra- telephonic stethoscope

Medical Devices & Surgical Technology Week. Atlanta:Nov 10, 2002. p. 7

Citation style: ProQuest Standard

Document 1 of 11

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Abstract (Summary)
With 140 million Americans in the work force, eDoc's current goal is to capture 1 percent of that market, or 1.4 million employees, said [Daryl Coker], a consultant for eDoc.

Full Text (1203 words)

A Dallas association management company began offering eDocAmerica.com to its nearly 100,000 members in April, finally propelling the Little Rock dot-com company to profitability.

Md Online LLC began peddling its service of answering medical questions by e-mail in 1997. Over the years, it has scrambled to sign up customers and been pressured into dropping its online prescription-writing service.

But now it's smooth sailing.

eDocAmerica boasts more than 140,000 patients at 335 companies across the country.

The company reported revenue of $300,000 in 2002, up from $250,000 in 2001. With the University or Arkansas system coming aboard this summer, eDoc is projecting revenue of nearly $600,000 this year and $1.5 million in 2004.

When Md Online entered the market, there was no such thing as a company designed to give medical advice and routine diagnosis through e-mail. Times have changed.

Other companies and hospitals, including the Cleveland Clinic and Massachusetts General Hospital, recently have announced they are offering online consultations.

Some people are even predicting these "e-doctor" services will help slow rising health care costs by reducing office visits. One study showed that by 2010, more than 20 percent of all office visits could be eliminated by a patient asking a physician questions online.

Not all doctors are giving these services a clean bill of health.

"I think it's horrendous," said Dr. David Goldstein, co-director of the University of Southern California's Pacific Center for Health Policy and Ethics. "I think it's unethical to promote that as something that can aid patients in the interest of building business or garnering subscribers."

Dr. Charles Smith, president and CEO of eDoc, said his service is designed to educate and coach patients.

"We really can't provide patient care to patients that we've never seen," he said.

Instead, eDoc is improving and enhancing medical care that the patient has already received, he said.

Patients have their own doctors perform exams and write prescriptions. Then eDoc is available to clarify their doctors' orders or answer other medical questions the patient might be too embarrassed to ask in person.

"(Patients) have a need after they leave that office for information," Smith said.

eDoc has 10 board-certified physicians and one psychologist on staff to field questions through a secure Web

site.

Most questions are answered within 24 hours.

Beginnings

Over the past decade, Smith had been working with computers while juggling his practice.

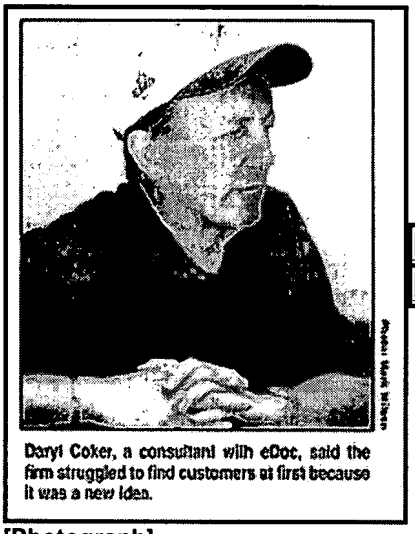
Smith, who has been in practice for about 30 years, saw that doctors don't have enough time to spend with their patients and patients sometimes don't understand the doctor's orders.

"So my thought would be to create another tier in the health care system that would complement the rest of the system, not replace it," Smith said.

And some patients drag themselves to the doctor's office when their question could have been answered over the phone or through e-mail.

For those reasons, eDoc was born.

"The nice thing about eDoc is that patients could log onto our system and ask our physicians many if not most of those same questions," which would prevent a trip to the doctor, Smith said.



Daryl Coker, a consultant with eDoc, said the firm struggled to find customers at first because it was a new idea.

Enlarge 200%
Enlarge 400%

[Photograph]
Daryl Coker, a consultant with eDoc, said the firm struggled to find customers at first because it was a new idea.

Physicians could take as much time as they needed to find the answers.

"Just imagine how valuable that would be - to essentially have second opinions or clarifying opinions or reactions to virtually everything that you come across in the health care system," Smith said.

eDoc was hatched in the University of Arkansas for Medical Science's BioVentures, a business accelerator designed to help technology-based startup companies. The idea quickly spread.

Enlarge 200%
Enlarge 400%

[Photograph]
eDoc Chief Operations Officer Mickey Miller, left, and Dr. Charles Smith, the firm's president and CEO, say they've finally lined up enough customers for the company to work.

Equity Capital Corp. of Little Rock began raising money for eDoc in November 2000 and bought the first two investor units at $25,000 each. UAMS and several of the doctors also pumped money into the company.

Equity President Max Hooper said in 2001 that Equity had planned on raising $5 million for eDoc, but Equity would probably stop raising the money when it reached $1 million.

"We believe it will be substantially profitable the first year," Hooper told Arkansas Business in April 2001. But it was two more years before eDoc saw a profit.

On Oct. 15, 2001, Md Online told the Arkansas Securities Department it had raised $787,500 by selling 31.5 shares at $25,000 each. The company also told the Securities Department that it was finished selling shares.

Part of the reason the company was slow getting out of the gate was no one had ever heard of that type of service, Smith said.

"We're essentially creating a market that never existed before," Smith said. "That is a slice of a health care benefit package that most companies don't really understand."

Another stumbling block to sales was most companies would only consider buying at the same time of year when the company typically settles on its health insurance plan for the coming year.

"So you have to get in line for their sales cycle," said eDoc President Robbie Linn. "So we typically plan about a year lead time [to make a sale.]"

eDoc has spent the last two years wooing companies to buy its service.

"It's those relationships and time frames that are now coming to fruition," Linn said. "I think we're well-positioned as we move forward."

Another minor blow to the company came in March 2002 when it reached the agreement with the state Medical Board to stop writing prescriptions over the Internet for patients in Arkansas.

Linn said it wasn't that big of a deal because fewer than 10 percent of eDoc consultations resulted in prescriptions anyway.

"It has no impact on our business," he said.

Picking up business

The company has been picking up steam since January 2001, when it had fewer than 24 corporations signed up. A year later, eDoc had about 130 companies, and now it has 335.

The company that pushed eDoc from the red to the black was Specialized Association Services of Dallas, an

association management company that represents numerous trade associations.

eDoc said it needs about 50,000 covered lives to break even. Before SAS came on board, eDoc had about 40,000 lives.

eDoc's strategy to attract more clients is to target four markets: employers, association and affinity groups, insurance companies and mass marketers.

With 140 million Americans in the work force, eDoc's current goal is to capture 1 percent of that market, or 1.4 million employees, said Daryl Coker, a consultant for eDoc.

The main selling point to employers is eDoc can cut down on the number of doctor office visits employees schedule for routine diagnosis and advice.

eDoc's statistics show its service eliminates 25-33 percent of office visits. For the price of about $1.25 per employee per month - or less, depending on the number of employees - participants get unlimited access to a secure Web site to ask medical questions.

He said the Internet doctors should have a disclaimer when offering advice, saying there are a number of diseases that could be suggested by the symptoms a patient mentions.

Indexing (document details)

Subjects:	Online information services, Colleges & universities, Contracts, Revenue, Financial performance
Classification Codes	9190, 3100, 8331, 8306
Locations:	Little Rock Arkansas
Companies:	eDocAmerica.com (**NAICS:** 519190) , University of Arkansas System (**NAICS:** 611310)
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Document 2 of 11

Arkansas Regulators Crack Down on Internet-Based Medical Services Firm
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regulators.

They then fill out an online questionnaire similar to those handed out in actual doctors offices that give physicians the information they need to give basic health advice, Linn said. Correspondence between patient and physician takes place over a secure Internet connection on the eDocAmerica Web site. If the eDocAmerica physician does grant a prescription, he faxes it to the pharmacy of the patient's choice.

Full Text (757 words)

Mar. 22--A Little Rock dot-com firm that offers medical services over the Internet recently ran afoul of state regulators, who took a dim view of the company's willingness to fill prescriptions based on e-mail correspondence.

MD Online LLC immediately bowed to pressure from the Arkansas Medical Board and agreed to stop offering the service inside the state. The company's Web site, eDocAmerica.com, offers health advice to the employees of companies that pay for the service.

Although filling Internet prescriptions isn't a major part of the 3-year-old company's business -- the company's president said the loss of the service will barely have an impact on his bottom line -- it is a touchy area for regulators across the country, who have watched a generation of drug dispensers bloom on the Internet in the past few years.

"There seemed just to be a kind of explosion of these Web sites," said Lisa Robin, assistant vice president of leadership and legislative services for the Federation of State Medical Boards, which maintains a database on Internet drug sales.

A host of Web sites now offer any number of drugs on the Internet, with most asking for credit card numbers, not prescriptions. Particularly popular are sites that sell drugs meant to end either hair loss or weight gain, treat depression or help men with sexual difficulties.

Regulators say doctors should only offer prescriptions after meeting a patient face to face and gain a firsthand understanding of the patient's problem and history. Regulators add that offering prescriptions over the Internet is a risky business that leaves physicians at the mercy of patients, who may lie to get the drugs they want.

"Utilizing just the computer, how do you know the patient really exists and is telling the truth about themselves?" asked Bill Trice, an attorney who represented the state Medical Board in its discussion with MD Online. "It's a very dangerous process to let a physician diagnose you and prescribe treatment for you if you've never seen the physician."

The Medical Board is not pursuing legal action against the company, Trice said.

In July 2000, a Marianna doctor drew fire from authorities in Michigan for offering drugs over the Internet. At the time, the physician defended his actions, saying he offered needed drugs in a safe and private manner.

Michigan Attorney General, Jennifer Granholm, took a different view, calling him "no better than a street-corner drug pusher."

Robbie Linn, president of MD Online, stresses that online prescriptions are a very small part of his business -- eDocAmerica still fills prescriptions from outside Arkansas -- and that the company is happy to cooperate with regulators.

"There are places where you can go and get Viagra and weight- loss pills and all types of things that are very

inappropriate for the Internet," Linn said. "We denied far more prescriptions than we ever wrote."

All subscribers to eDocAmerica must be employees of companies contracting with MD Online and must first register with the service.

They then fill out an online questionnaire similar to those handed out in actual doctors offices that give physicians the information they need to give basic health advice, Linn said. Correspondence between patient and physician takes place over a secure Internet connection on the eDocAmerica Web site. If the eDocAmerica physician does grant a prescription, he faxes it to the pharmacy of the patient's choice.

MD Online is a company created from research conducted at the University of Arkansas for Medical Sciences. Several of the company's doctors are on staff at the medical center.

Supporters of online medicine say its advantages are too great to ignore.

Jeff Simek, vice president of public affairs for merckmedco.com, the online wing of pharmaceutical giant Merck and Co. Inc., listed several advantages of offering prescriptions online.

"Our members can pick up a phone and talk to a pharmacist seven days a week, 24 hours a day," Simek said. "Access to care is never more than a phone call away."

In the three years since the launch of merckmedco.com, sales have increased sharply. In the fourth quarter of 2001 alone, the site filled 2 million prescriptions, 60 percent more than the year- earlier quarter.

MD Online's Linn remains optimistic about the future of his business and online health services.

"I think we will find the whole thing evolves over time, just as a lot of areas of health care have," Linn said. "It's a learning process."

Credit: Arkansas Democrat-Gazette, Little Rock

Indexing (document details)

People:	Linn, Robbie
Companies:	MD Online LLC
Author(s):	Jake Bleed
Publication title:	Knight Ridder Tribune Business News. Washington: Mar 22, 2002. pg. 1
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Document 3 of 11

The internet
R Al-Shahi, M Sadler, G Rees, D Bateman. **Journal of Neurology, Neurosurgery and Psychiatry.** London:Dec 2002. Vol. 73, Iss. 6, p. 619-28

Abstract (Summary)
The growing use of email and the world wide web (WWW), by the public, academics, and clinicians-as well as the

increasing availability of high quality information on the WWW-make a working knowledge of the internet important. Although this article aims to enhance readers' existing use of the internet and medical resources on the WWW, it is also intelligible to someone unfamiliar with the internet. A web browser is one of the central pieces of software in modern computing: it is a window on the WWW, file transfer protocol sites, networked newsgroups, and your own computer's files. Effective use of the internet for professional purposes requires an understanding of the best strategies to search the WWW and the mechanisms for ensuring secure data transfer, as well as a compendium of online resources including journals, textbooks, medical portals, and sites providing high quality patient information. This article summarises these resources, available to incorporate into your web browser as downloadable "Favorites" or "Bookmarks" from www.jnnp.com, where there are also freely accessible hypertext links to the recommended sites.

Full Text (7532 words)

[Headnote]

J Neurol Neurosurg Psychiatry 2002;73:619-628

The growing use of email and the world wide web (WWW), by the public, academics, and clinicians - as well as the increasing availability of high quality information on the WWW - make a working knowledge of the internet important. Although this article aims to enhance readers' existing use of the internet and medical resources on the WWW, it is also intelligible to someone unfamiliar with the internet. A web browser is one of the central pieces of software in modern computing: it is a window on the WWW, file transfer protocol sites, networked newsgroups, and your own computer's files. Effective use of the internet for professional purposes requires an understanding of the best strategies to search the WWW and the mechanisms for ensuring secure data transfer, as well as a compendium of online resources including journals, textbooks, medical portals, and sites providing high quality patient information. This article summarises these resources, available to incorporate into your web browser as downloadable "Favorites" or "Bookmarks" from www.jnnp.com, where there are also freely accessible hypertext links to the recommended sites.

"There are billions of neurons in our brains, but what are neurons? Just cells. The brain has no knowledge until connections are made between neurons. All that we know, all that we are, comes from the way our neurons are connected." Tim Berners-Lee, Weaving the web1

The internet-the largest network of computer networks-is the most important development in global communication since both the television and the telephone. The internet offers high speed communication and up to the second information in a cheap, user friendly medium. Access is potentially universal, notwithstanding the digital divide between developed and developing countries caused by a lack of hardware and telephone lines.2 However, the internet is often maligned for being an unsafe, unstructured, uncontrollable occupational hazard with strange customs and jargon, which is time ineffective because of its low signal to noise ratio and potentially addictive nature (www.netaddiction.com).

The challenge now is not to get on line but to keep abreast of developments in internet technology and health information delivery to both professionals and patients, and to make the most effective use of them. This series of review articles and subsequent Neuronline fillers are intended to help with that process. Although the nature of the internet prevents this review from being comprehensive, the review aims to provide and build on a basic knowledge of the internet, with a focus on email and the world wide web (WWW), and with a slight bias towards content from the United Kingdom. If you are a newcomer to the internet you may wish to refer to table 1 and to supplement this article by reading a general guide to the internet3 or existing review articles.4-8 There are also guides to the internet specifically for doctors such as the Internet Medic section of the Resource Discovery Network (www.vts.rdn.ac.uk) or Medicine and the internet.9

SEARCH STRATEGY

This article is based on our own knowledge and a search of the following:

* Ovid Medline (1966 to 1 August 2001) for review articles in the English language in which the medical subject heading terms "Computer communication networks" and "internet" were the focus (http://biomed.niss.ac.uk);

* The WWW;

* The British Medical Journal's medical informatics collected resource (www.bmj.com/collections).

ORIGINS OF THE INTERNET

The origins of the internet date back to the launch of the Russian satellite Sputnik in 1957.10 The subsequent fear of the cold war becoming nuclear prompted the American government one year later to fund the Advanced Research Projects Agency (ARPA) to develop a means of electronic communication to secure American military technological superiority (www.isoc.org/internet/history/brief.shtml).

Two ways of broadening computer accessibility were time sharing-which enabled one computer to divide its processing capacity between different users connected to it simultaneously-and linking computers to form a network. The obstacle to developing networks was the incompatibility of their diverse operating systems. ARPA overcame this by developing a core network of identical interconnected computers, each known as an interface message processor, to which computers with diverse operating systems could connect to form the "ARPANET". Data were transmitted within this network, as they still are now, using an innovation called packet switching, in which messages are broken into equal packets each labelled with a header identifying its source, its destination, its position in the sequence, and whether the packet had become corrupted in transmission. Interface message processors routed messages, reassembled them at their destination, and re-sent them if they were corrupted in transit. In such a decentralised, distributed network, bottlenecks could be avoided and even the loss of portions of the network would not prevent the flow of information. When ARPANET was launched at the end of 1969, there were four nodes, but by the end of 1972 there were 37 nodes across the United States. The network was extended across the Atlantic the following year.

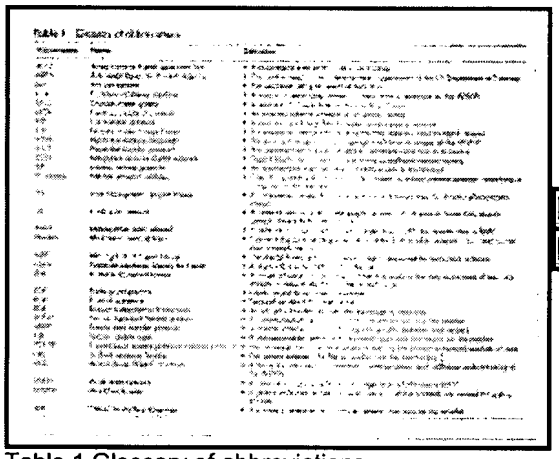

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Table 1 Glossary of abbreviations

As other networks of varying reliability were developed-predominantly in academic and military institutions-a unifying method of interconnecting them was needed. This was achieved by using gateways (called routers) between the separate networks that understood the protocols used by computers communicating across them and the now standard method of packet switching, called transmission control protocol/internet protocol (TCP/IP). IP handles the naming, addressing, and routing of packets, leaving TCP to split data, wrap them in virtual envelopes, reassemble them in the correct order at the destination host, and request retransmission of any packets that are lost or corrupted.

The internet has a hierarchical network structure linked through a backbone of supercomputers permanently joined by high speed optical cable connections, which traverse land and ocean. Metropolitan (MANs) and wide area networks (WANs) provide higher performance for larger geographical areas, being less dependent on the backbone. Local area networks (LANs) serve organisations such as the NHS in the United Kingdom.11 LANs usually comprise their own private secure network (intranet), which can support any computer or device such as a printer (an ethernet), and which can be extended to other organisations over the internet using secure connections (extranet) (fig 1). Internet service providers (ISPs) link individual users to the internet through national point of presence (POP) networks in their vicinity.

ARCHITECTURE OF THE INTERNET

The terms "internet" (or "the net") and "world wide web" (or "the web") are often used interchangeably as if they were synonymous, without appreciating that the WWW is one of many services available on the internet. These other services include email, file transfer protocol (FTP), network news, Telnet (a means of accessing a remote,

networked computer), and instant messaging (a means of detecting when others are connected to the internet and sending them a text message, approximating a real time conversation). Although telemedicine uses electronic communication technologies to deliver and support health care over long distances (http://tie2.telemed.org) the internet is not the main method used, so we will not deal with it further.

The world wide web

The WWW accounts for the majority of internet traffic. Tim Berners-Lee invented it at the European Centre for Nuclear Research (CERN) in 1989-90 as a means of sharing and cross referencing physics research in a consistent format.1 While the underlying structure of the WWW has hardly changed since its invention, its function has developed enormously.

Browsers are software applications that create a user friendly virtual window on many of the internet services, behind which their different communication protocols are kept well hidden. The launch of the Mosaic browser in 1993 was the revolutionary development largely responsible for popularising the WWW; it could handle graphics as well as text, and navigation merely involved pointing and clicking with a mouse, rather than knowledge of the UNIX programming language. Browser technology is continually developing (www.browsers.com). The two main browsers are Microsoft Internet Explorer (www.microsoft.com/window/ie) and Netscape Navigator (http://browsers.netscape.com). The current browser series for use with recent operating systems is 6.x (the decimal after the series number indicates the particular version, denoting new features and fixed program bugs).

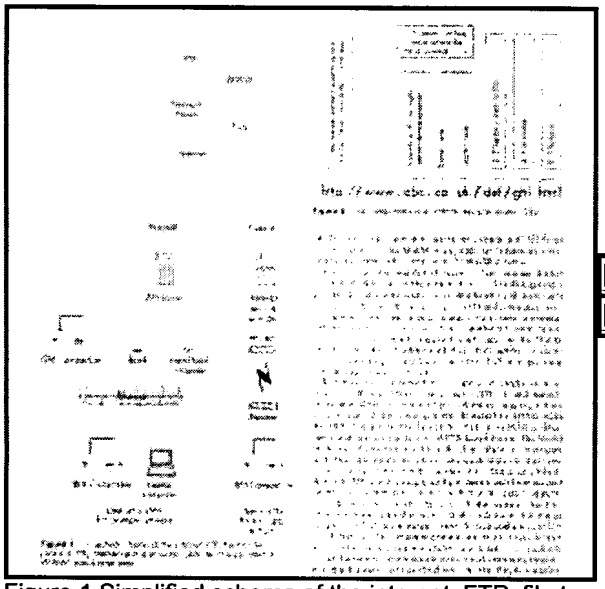

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Figure 1 Simplified schema of the internet. FTP, file transfer protocol; ISP, internet service provider; LAN, local area network; WWW, world wide web.
Figure 2 The components of a uniform resource locator (URL).

Pages on the WWW are held on servers (computers dedicated to sending, storing, or receiving information, usually permanently connected to the internet). The content and style of pages on the WWW were originally written exclusively in hypertext markup language (HTML), the pages were connected by hypertext links, and hypertext transfer protocol (HTTP) was used to transfer a web page written in HTML from server to browser. This WWW went public on 15 January 1991, and by November 1992 there were 26 WWW servers.

However, as the number of servers grew, unique dotted decimal IP addresses in the format 111.222.333.444, giving a possible 4.2 billion locations, were developed to identify each host server. Because humans prefer words and computers prefer numbers, invisible domain name servers now automatically translate exclusive case sensitive uniform resource locators (URLs)-developed to identify each page on the WWW (fig 2)-into the IP address of their host server. A client browser uses the path and file names in the URL to request the specific page from the server.

Text has been enhanced by a variety of media such as images (GIF and JPEG), video clips (MPEG), and sounds (WAV and MP3). A variety of programming languages have since enhanced the static content delivered by HTML

with dynamic and interactive functions, such as searching databases and submitting data on WWW based forms. The World Wide Web Consortium (W3C) develops these technologies and their specifications, and issues guidelines on their use (www.w3.org). For example, JavaScript is a language embedded in HTML that is interpreted by a client's web browser and enables simple functions such as a change in a page's appearance in response to the location of the cursor. Another language, Java, is used to write small applications known as "applets", which are separately downloaded and executed by a web browser. The common gateway interface (CGI) defines how forms dependent on client side input (for example search facilities) communicate with servers running interactive applications such as databases. A structured, semantic WWW will be developed in the future using machine readable languages such as resource description framework (RDF) and extensible markup language (XML) to enable, for example, simple translation of web sites (http://babelfish.altavista.com).

To make the most of the WWW, there are several simple ways to enhance your browser use, which will make your online experience easier, quicker, and more controllable (table 2).

Electronic mail (email)

Email rivals post, facsimile, and telephone as the fastest, cheapest, most accessible, and most convenient way of transmitting text and files of any format between one or many networked computers.7 The format of an email address is person@hostname, where the host name is the domain name of the internet host. Most email is accessed purely on the WWW (web mail) or through ISPs providing a mail server (POP mail) conveying emails that are read in an email viewing program. Popular web mail among doctors in the United Kingdom registered with the General Medical Council is available through www.doctors.net.uk, which is also a portal (see below) for medical information. Many people have more than one email address, which can be aggregated by viewing programs as well as web mail (www.mail2web.com), provided you have your POP mail server name, username, and password for each account. Email can also unify other commonly used methods of communication such as fax and voice mail by converting these messages into an attachment (www.j2.com).

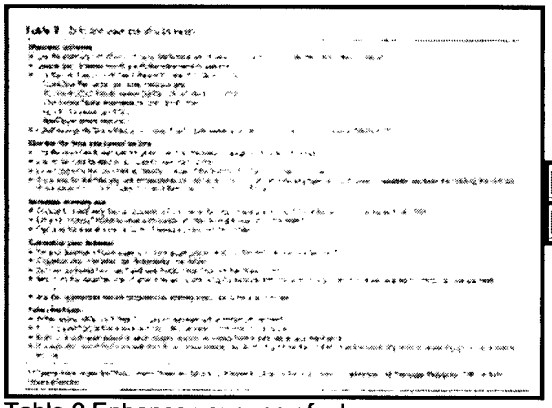

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Table 2 Enhance your use of a browser

File transfer protocol

FTP is the most efficient method of transferring documents and software over the internet. A resource can be compiled on a remote server and a recipient can retrieve files from that resource at their leisure (rather than suffering a prolonged download time by email or waiting for a disc to arrive by post). Although there are programs dedicated to handling FTP (called FTP clients), modern web browsers are able to perform the same functions. Files are often compressed to economise on server space and speed transmission using freely available software (for example, www.winzip.com). While access is restricted to some FTP sites, anonymous FTP sites offer free files and software-called freeware and shareware-that can be searched using Archieplex (http://archie.emnet.co.uk).

Network news

There are close to 100 000 newsgroups, which are accessible from news servers (available on most networks and ISPs, although often in reduced numbers). Newsgroups can be viewed with a newsreader program but more often the multipurpose web browser is used. Newsgroups are indexed by http://groups.google.com. Newsgroups are similar to a bulletin board: discussion topics (called threads) are started in the relevant newsgroup and

participants post opinions. There is considerable flexibility in the system, as observers choose which threads and messages to retrieve or censor, and which participants to censor, especially if they do not obey "netiquette" (see below). The lifetime of messages can be short to economise on the server space used to store them.

INTERNET ACCESS AND PERFORMANCE

The three fundamental requirements for internet access are a computer, a connection to the internet (via a LAN at work or an ISF at home), and web browser software. Attributes of the computer and your connection, in addition to the volume of internet use at the time, determine the speed and reliability of your access to the internet.12

The connection capacity is known as bandwidth and is rated in bits per second (bps). Dialup modems arc the commonest means of accessing the internet from home; modems convert digital into analogue signals suitable for transmission through a telephone network and convert received analogue signals back into digital data. Modern telephone modems are rated at 56 000 bps (or 56 Kbps), and with eight bits in a byte (each byte determining one character), they can transmit seven kilobytes-or 7000 characters-per second, although 32-40 Kbps is the best seen in practice. Faster access, continuous connection, and simultaneous telephone access are provided by pure digital services offering broader bandwidth (broadband), which also eliminate the ~30 second dialup modem connection time. Integrated services digital network (ISDN) and asynchronous digital subscriber line (ADSL) use telephone lines with modified hardware to send digital signals-without the need for analogue transformation-at capacities of up to 128 Kbps and 6 Mbps, respectively. Cable and satellite also offer broadband telecommunications of 1-10 Mbps. These and wireless networks (such as www.bluetooth.com) are the emerging telecommunications for the internet, but they are costly for now, some require bandwidth to be shared with one's neighbours, and access is limited in some countries and in rural areas.

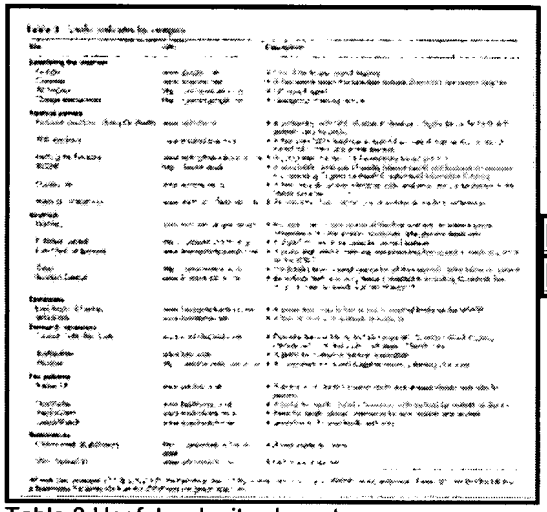

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Table 3 Useful web sites by category

If you connect to the internet via an ISP, performance will also be determined, in part, by which internet backbone (s) the ISP connects to, what connection speed they support, and whether there is a local POP server. Moreover, the greater the bandwidth between your computer and your ISP's server, the more the speed of internet access is limited by the speed of the connection between your ISP's server and the other servers making up the backbone of the internet. All ISPs should provide POP email addresses and some also provide a few megabytes of server space where you can post a web site. Attention should be paid to whether there is a charge for setup and the expense of calls for customer support and to dialup (do they charge local rates only and are off peak discounts offered?). For example, in the United Kingdom free access is possible because local calls are metered, and an ISP would gain revenue from your telephone bill and often astronomical helpline rates. Web sites have grown up to specifically inform consumers about the relative merits of the wide variety of ISPs (for example, www.ispreview.co.uk).

Once you've established a satisfactory connection to the internet, the resources available can revolutionise your life, if you know where to find them and how to make the most of your online experience. In the following sections we discuss issues likely to concern the JNNP readership, we describe ways of enhancing the use of the WWW and email, and we provide a directory of web sites of general medical interest (table 3).

MEDICAL CONCERNS ABOUT THE INTERNET

The quantity of medical information on the internet and the escalation of its use by both providers and consumers of health care have led to specialists in "cybermedicine" studying its application, impact, and evaluation.13 Two of their greatest concerns are security and the quality of information, for both patients and doctors.

Security

Security was not a major concern in the original design of the internet. The communications protocols underlying the WWW (HTTP) and email (simple mail transfer protocol (SMTP)) leave communication open to interception by traversing many different computers, which has led to the use of encryption (in which a message is encoded by the sender and decoded by the receiver). Because the online community sees the main methods of encryption as potentially vulnerable to covert surveillance by government agencies who know how they work, other security measures have developed.

The transmission of health related data in particular should be confidential, unmodified, authenticated, and impossible to renounce.14 The responsibility for this rests with administrators running networks and servers as much as it rests with individual users. These standards pose a challenge for electronic patient records projects (although they avoid the drawbacks of paper based records being unavailable, incomplete, and insecure)15 but electronic records do require coding systems, standard communication protocols, and secure electronic protection, for example, using smart cards.16 17 While a secure WAN called NHSnet (www.nhsia.nhs.uk/nhsnet) is being developed in the United Kingdom with expanding capabilities in this area, one web site provides dedicated electronic medical records for a fee (www.personalmd.com).

Theses issues aside, to maximise the security of communication over the internet, there are a few key precautionary measures to take, depending on the medium.

The world wide web

The most widely used encryption algorithm is 128 bit key RSA (named after the initials of its inventors), which relies on mathematical properties of large prime numbers. KSA is used by Netscape Communications' reference standard secure sockets layer (SSL) protocol and the secure hypertext transfer protocol (SHTTP) developed by CommerceNet. A URL that begins with "https://" means that the server is secure, indicated by a closed padlock image on the status bar of your browser. It is your responsibility, however, to ensure that SSL is activated in the Options/Properties menu of your browser; the server checks only that you enter the SSL port and not whether your browser is actually using SSL.

Other security measures you can take for browsers are using the current version of your browser (which would be compatible with the latest security software and have known security risks protected), setting a medium to high level of security (in Tools/Internet Options), disabling AutoComplete functions for forms (to stop your browser storing your passwords), and disabling embedded client side programming languages (such as Java), which would otherwise expose your browser to threats from applets that can exploit the data on your computer.

Lastly, "cookies" deserve special mention; they are small files placed on your computer by a web site host server (www.cookiecentral.com). Because some IP addresses are not static but are dynamically allocated (for example, when you dial in to an ISR addresses are allocated from its limited pool of IP addresses), cookies were developed to enable their web site of origin to recognise a specific returning user. By aiding recognition, cookies speed up logging into password protected zones and allow personalisation of WWW content, but they also help web site developers to assess their site's traffic and monitor viewing habits. Clearly, using cookies is unwise on shared computers but it is a matter of personal preference as to who accepts them and whether you enable the cookie alerting mechanism in your browser. The only cost of greater security, of course, is that you will be unable to benefit from the enhancements offered by cookies and Java applets.

Email

Although emails can potentially be intercepted, the sheer volume of internet traffic makes this unlikely, unless your account is specifically surveyed, for example, by administrators with access to your incoming mail server. In countries where email monitoring by employers is legal, interception cannot be prevented. However, email can be

rendered decipherable to only its intended recipients by using public-private key encryption methods. One example is a new freely downloadable format called pretty good privacy (PGP), available from www.pgpi.org. The legality of using encrypted email for the transmission of patient identifiable data is, to our knowledge, as yet untested in the United Kingdom.

The other main email security issue is the inadvertent receipt of malicious programs that are designed to extract themselves and spread, called viruses, Trojan horses, worms, or blended threats, which are combinations of them. When a user performs an action (such as opening an email attachment), a virus may infect other programs or hidden system files, a worm replicates itself over a network (for example, by sending itself to all contacts in an email address book), and a Trojan horse opens a port to the internet to allow unauthorised access to your computer or network. In the main, these threats can be avoided by not opening email from suspicious senders or suspicious attachments from known contacts. Additional protection can be provided by installing a personal or network firewall, which is software or hardware, or a combination of both, that protects incoming (and outgoing) traffic and ensures that only authorised ports are visible to the internet (www.zonelabs.com). The other essential measure is to install virus protection software and keep it up to date (www.symantec.com or www.nai.com).

Finally, once you have an email address you may receive unsolicited junk mail ("spam") from advertisers, who use sophisticated software to scavenge your email address from sources on the internet. This likelihood is increased if you sign up to public newsgroups, discussion forums, or email directories. A prudent strategy is to have at least two email addresses, one of which is solely for personal mail.

Information quality

Freedom to publish on the WWW is responsible for its best and worst characteristics: valuable innovation diluted by extraneous information. Although high quality information is promoted by various organisations such as the Health for Help Trust (www.hfht.org), it seems that high quality information about common conditions is often difficult to find, incomplete, and inaccurate and uses language that is too complicated.18

Because poor quality information about health is at best misleading, and at worst harmful, critical appraisal is necessary, but who should perform it? Patients would find an instrument to assess each web site they visit helpful. Although none of these assessment tools is validated,19 the following common sense quality criteria seem indisputable20: accurate, up to date, and comprehensive content; attributable and authoritative authorship; disclosure of competing interests; clear design; user support; and an assurance that personal health information submitted by users is kept confidential. For now, DISCERN (www.discern.org.uk) and the Health Information Quality Assessment Tool (http://hitiweb.mitretek.org/iq) are the best tools available for patients21 22 but how much they are used is unknown. Alternatively, patients can consult directories or portals that act as trusted third parties and filter content for the user (table 3).

Internet commentators are divided as to whether quality filters or standards and evaluation instruments should exist at all.23 If instruments are to be used, there are demands for evidence of their effectiveness.19 Future solutions include software that searches a web site's invisible metadata (assigned by its author) and a rating service for information about the web site's content and context.24

WORLD WIDE WEB RESOURCES

While web sites designed to find what you want on the WWW inevitably reflect the information available, their ability to recognise which web site is most relevant to your requirements has become excellent.

Search engines, subject directories, and search agents

The web sites that help you find your way around the WWW are freely accessible. They may be search engines (for example, www.google.com), which automatically scour the WWW itself for sites of relevance, directories of sites compiled and reviewed by the authors of the directory (for example, http://dmoz.org), hybrids of the two (for example, www.altavista.com), or search agents (for example, www.copernic.com).

Search engines are valuable for their sensitivity, whereas directories have a higher specificity.25 Up to date information on the relative merits of the various engines is available from a site called Search Engine Watch (www.searchenginewatch.com). At the time of going to press Google (www.google.com) and AllTheWeb

(www.alltheweb.com) vie for the largest and most comprehensive index.

Subject directories-also called gateways or portals-are usually indexed in a hierarchical file structure and are rated by the people who compile them, so local information is best found on the regional version of the directory (for example, http://uk.yahoo.com, rather than www.yahoo.com). Although directories have a health category, the highest quality medical information is to be found on specialist portals (below).

Crucial to finding the web site closest to your requirements is using search terms most specific to your needs, yet sensitive enough not to miss anything useful. Most important, read the About section of the search engine or directory you choose to use. Engines can search for particular types of file (for example, web pages, sound files, and graphics), in certain languages, using suggested keywords and Boolean commands (to incorporate multiple terms, for example, or to exclude others).

Undoubtedly the most powerful method of finding the information you want is to use a search agent, such as Copernic (www.copernic.com), which automatically searches multiple search engines and directories with your search terms, removes duplicates, and compiles and ranks the results.

Medical portals

Search engines are best used with very specific search terms but they tend to return an overwhelming quantity of health information of generally poor quality with a general term, such as the name of a disease. The accessibility, format, and functionality of the WWW enable medical portals to come into their own in providing indexed, comprehensive databases of high quality information and they enable journals and even textbooks to be reproduced on line.26 27

However, there is a profusion of medical portals offering these collated resources to doctors, patients, or both (generally from North America with URLs beginning with www.med or www.MD). sometimes requiring a subscription. Because of the fierce competition in this area, the portals are subsuming each other (for example, www.medscape.com was recently acquired by tvww.webmd.com). Your country of origin will partly influence your choice of portal; HealthWeb (http://healthweb.org) and BIOME (http://biomc.ac.uk) are high quality resources in North America and the United Kingdom, respectively. The "list of lists"-the Hardin Meta Directory (www.lib.uiowa.edu/hardin/md)-is inevitably compendious but has a lower signal to noise ratio. Some portals, such as Doctors.net (www.doctors.net.uk), go even further to try to foster an online community by offering other services such as discussion forums, a searchable database of colleagues, a classified section, server space for document storage, and e-commerce.

In the United Kingdom, the National electronic Library for Health (NeLH) (www.nelh.nhs.uk) is a promising initiative aimed at delivering high quality information to improve patient care in the NHS.28 The NeLH is a gateway for staff in the NHS to access a variety of resources, primarily concerning evidence based medicine (available in even more detail from www.nettingtheevidence.org.uk). Whereas only the abstracts of reviews in the Cochrane Library arc available to anyone (www.update-software.com/cochrane/abstract.htm), the NeLH provides the entire contents of the Cochrane Library. Similarly, access to the entire contents of Clinical Evidence (www.evidence.urg) and Evidence Based On Call (vvww.ebon call.co.uk) are available through the NeLH. There arc links to PubMed (www.ncbi.nlm.nih.gov/entrez) and a comprehensive database of guidelines from among other sources the Scottish Intercollegiate Guidelines Network (www.sign.ac.uk), the National Institute for Clinical Excellence (www.nice.org.uk), and the National Guideline Clearing House (www.guideline.gov), based in the United States. If you do not have access to the NeLH, the TRIP database (www.tripdatabase.com) provides a free search of the main evidence based resources, peer reviewed journals, guidelines, and e-textbooks on the WWW.

Journals

Internet idealists see the WWW as the most revolutionary development in publishing since the printing press. Online repositories for articles, such as BioMed Central (www.biomedcentral.com) and PubMed Central (http://pubmedcentral.nih.gov), have embraced the ideal of free access for all to the medical literature.29 PubMed Central provides free access to some print journals already offering their entire contents on line (for example, www.bmj.com), in addition to the purely electronic journals in BioMed Central (for example, BMC Nuerology). Articles in these reservoirs of knowledge benefit from being indexed in PubMed, published the moment they are accepted, and their copyright is not transferred to the publisher. The site www.freemedicaljournals.com provides a

comprehensive list of medical journals, which are free either at the point of publication or after a delay (for example, JNNP has been published on line since 15 March 1999(30) and articles are free one year after print publication).

There are several other advantages of online publication, such as the speedy dissemination of netprints or preprints (research before, during, or after review by other agencies),31 WWW based supplements to print articles that are likely to improve the quality of reporting,32 and preprint servers that may help prevent publication bias.33 Hypertext links between reference lists from an article in one online journal and the original article in another and from portals directly to the online journal obviate the need for laborious journeys to the library. Online article submission (now available for JNNP) enables faster peer review and a seamless transition of an article in electronic format from submission to publication, with communication by email. Article citations can be down-loaded to reference management software or downloaded as portable document format (PDF) files with Adobe Acrobat (www.adobe.com/products/acrobat) for printing, indistinguishable from the paper version of the article. Moreover, because a browser's country of origin is recognisable from its IP address, free full text access can be delivered to resource poor countries.34

Lastly, journals' emailed tables of contents (eTOCs) and automatic alerts about articles on particular topics or by particular authors can result in a more time effective way of keeping up to date. Signing up for an eTOC is usually done through an online journal's web site, a subscription to the journal is not usually required, and removing oneself from the list is as easy as signing up. An excellent eTOC service, offered for any journal received by the British Library (whether or not the journal provides an eTOC of its own), is available from Zetoc (http://zetoc.mimas.ac.uk), which can be accessed freely via the NeLH.

Despite the myriad advantages, sceptics view online journals as a threat to the "integrity of the scholarly record of science"16 and resent the loss of the aesthetic appeal of a paper journal. Publishing houses fear a greater burden for peer review with easier article submission, loss of copyright, and lower revenue from print subscriptions, which are only slightly offset by online subscriptions and pay-per-article fees, themselves jeopardised by unlegislated information sharing technology (such as Napster and Gnutella). Given the spectrum of solutions adopted by medical journals to the pressure to provide access on line and the lack of knowledge about its impact, an e-journal user study is underway (http://ejust.stanlord.edu).

e-Textbooks

FreeBooks4Doctors (www.freebooks4doctors.com) is a portal dedicated to indexing textbooks that are freely available on the WWW, whether they are purely electronic or not. At the forefront, eMedicine (www.emedicine.com) is a comprehensive, entirely WWW based e-textbook and portal, requiring only registration (and not a paid subscription). Despite the appearance of sponsors and advertising on the web site, authors are independent of the pharmaceutical industry. UpToDate (www.uptodate.com) is an independent e-textbook but it requires a subscription. The vast majority of printed medical textbooks with an online version require a subscription, such as Harrison's Online (www.harrisons online.com), which is an expanded, continually updated, cross referenced version of the 15th edition of Harrison's principles of internal medicine. Other textbooks, such as the Oxford textbook of medicine, are available for purchase only as a CD ROM.

Research

In addition to the medical portals that compile evidence based resources and journals for use in routine practice, which are equally applicable to the needs of researchers, national and international repositories of research activity are of particular value. Registries of ongoing and completed studies are important to prevent unnecessary duplication and publication bias, and can provide paradigms for other areas where research is needed. For example, the National Research Register compiles data about research activity in the United Kingdom (www.update-software.com/National), while Current Controlled Trials (www.controlled-trials.com) and Centerwatch (www.centerwatch.com) collate information about randomised controlled trials in particular. Funding resources are even more specific to your country of origin, but the Wisdom database run by the Wellcome Trust is the best starting point in the United Kingdom (hup://wisdom.wellcome.ac.uk).

Patients

Because internet access and usage arc rising dramatically and health is one of the main categories of information sought, the provision of high quality patient information is essential. Although some have doubted the importance

of this phenomenon,35 a recent survey found that a quarter of patients with home access to the internet used medical web sites before consultation at a neurology clinic, and this information was inappropriate in 60% of cases.36 Because misinformation may be harmful due to incorrect self diagnosis, inappropriate treatment discontinuation, or self medication and because of the potential of the internet to encourage suicide, organisations exist to monitor health fraud on the WWW (www.quackwatch.com).

The Health On the Net Foundation (www.hon.ch) is a not tor profit organisation to guide patients (and medical practitioners) to useful and reliable online health and medical information, guided by their established code of conduct. Possibly the best web sites for providing patients with information about the whole range of medical conditions are www.patient.co.uk, www.healthsites.co.uk, and www.medicdirect.co.uk in the United Kingdom and www.healthfinder.gov in the United States.

EMAIL

Professional use

Email is the most effective way to keep up to date with journals' eTOCs, which arc often sent before print publication. Many professional associations' web sites offer similar email alert services to maintain awareness about meetings and newsletters and to provide a simple way to register and submit abstracts for conferences. Email is also being used by journals to speed up the process of peer review using WWW based systems.

For those less daunted by large scale communication, mailing lists, ncwsgroups, bulletin boards, web forums, and the notorious chat rooms offer online communities in which peers can exchange news, opinions, and comment. Mailing lists are usually administered by a host institution and use software such as Listserv (www.lsoft.com) to circulate emailed contributions to a discussion on a particular topic. Join a list by simply sending an email to the administrative address (the membership of some lists is vetted). Anonymity is maintained unless you wish to contribute and content is usually moderated. A good starting point would be the Medicine and Health category at www.jiscmail.ac.uk. Newsgroups (such as misc.health and sci.med, available via http://groups.google.com), bulletin boards, and web forums (www.theabn.org/training) offer a similar, but web based, means of communication that does not clog your email inbox.

The online doctor-patient relationship

As public use of email expands there is considerable potential for the doctor-patient relationship to be electronic. While such email correspondence is not critical to medical practice and unlikely to be a substitute for at least an initial consultation in person, there are conceivable benefits and predictable drawbacks, which still require further research.37

As an asynchronous medium, email enables correspondents to respond at their own convenience in a time effective manner, averaging four minutes per email in one study.38 Email avoids the need to return missed telephone calls. Email is also likely to be cost effective by minimising outpatient attendances, but this has not been evaluated. Email is said to be less intimidating for patients than a face to face encounter and may enable them to discuss sensitive issues more freely, while it enables the doctor to provide a considered, documented response. Of course, email misses the subtleties of communication in person.38

There are drawbacks to doctor-patient email but they should be viewed in the context of the medical profession's initial reluctance to adopt the telephone as a means of communication." Doctors are sceptical mainly about the workload that email may generate; time spent on this may be managed by having an email account dedicated to patient correspondence. There are potential legal liability issues and strong arguments for privacy and confidentiality, which require encrypted communication. Furthermore, if email communication about health care becomes commonplace, patients who are not on line may become disenfranchised.

The American Medical Informatics Association has proposed contractual guidelines for the doctor-patient online interaction.40 We have summarised these guidelines in table 4 but they apply only to an already established doctor-patient relationship. They do not address unsolicited email,41 nor what doctors' conduct should be in mailing lists, bulletin boards, chat rooms, and newsgroups involving patients. In all circumstances, it is wise to heed the informal code of conduct, known as nctiquctte (www.albion.com/netiquette), which is largely a reminder to interact as you would in other media but also to respect others' privacy and bandwidth.

INTERNET FUTURES

The internet will become omnipresent and so transparent that it will be taken for granted as much as electricity is in the developed world. The future aims of internet technology are embodied by the goals of the W3C: to enable universal access, establish a "semantic web" with meaning using machine readable languages, establish enhanced security, avoid software incompatibility, ensure that technologies are evolvable, preserve the distributed decentralised nature of the internet, and encourage more interactivity and richer multimedia.

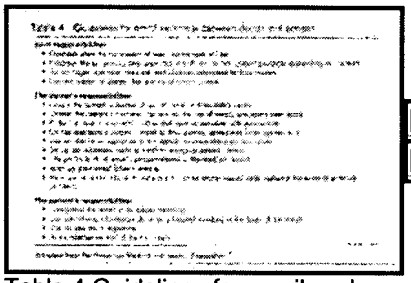

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Table 4 Guidelines for email exchange between doctor and patient

The most immediate challenge for the next generation internet (www.ngi.gov) is to support increasing demand for both access and greater speed. In the next few years advances in fibre optic technology will hugely increase the capacity of the backbones as they become more extensive, perhaps even to the interplanetary internet (www.ipnsig.org). Dialup modem access will soon become a thing of the past as "always on" broader bandwidth alternatives (such as cable, satellite, digital subscriber line, and T1 and T3 networks) pervade the developed world. Wireless data services in the 1-2 Mbps range (www.wireless.com) may obviate the need for fixed cabling. The 4.2 billion potential IP addresses are fast running out, heralding the next addressing standard, Ipv6, which will allow a staggering 6 × 10^sup 23^ internet addresses per square metre of the Earth's surface, with built in security and automatic address allocation.

In medicine, it is likely that additional change will be partly driven by patients changing from passive recipients of health care to active consumers, in greater electronic contact with their doctor through email or telemedicine." Optimists believe that increasing consumer and provider involvement will drive an improvement in the quality of health care.13 The American Medical Informatics Association has already envisaged the future and established three bold goals for 2008: a virtual health care databank, national health care knowledge bases, and a personal clinical health record.42 But despite the overwhelming urge to develop something because of the ability to do so, the time honoured principles of evidence based medicine are likely to be needed to ensure that future internet developments have a beneficial impact on health care.27

CONCLUSION

The internet has expanded from defence to academic, commercial, and medical institutions, is now global, and is increasingly accessed at home. The greatest threats to our use ol the internet will be expensive telecommunications, intellectual property rights, and data protection regulation.16 Most of all, the expansion of web sites, mailing lists, and discussion forums will make an up to date knowledge of the best resources mandatory, for which this and subsequent review articles serve as a baseline, with updates in the JNNP's monthly Neuronline section.

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E-healthcare: A vehicle of change

Binshan Lin, *Daniel Umoh*. **American Business Review**. West Haven:Jun 2002. Vol. 20, Iss. 2, p. 27-32 (6 pp.)

Abstract (Summary)
The explosion in the use of electronic communication technology in all walks of life this past decade has had a tremendous effect in society and health care system is at the forefront of this. The Internet is one important example of how the application of electronic communication technology continues to advance health care. A survey done by harrisinteractive.com, the Internet arm of Harris market research and polling, found that eighty-six percent of Internet users said they were scanning the web for healthcare and disease-specific information-up from 71% in 1999. The introduction of electronic technology devices in surgical procedures, the exchange of electronic information, and the ability of the hospitals to order supples directly using the manufacturers' computer terminal and the timely delivery of the product(s), to mention just a few, attest to its affect on the healthcare system as a whole.

Full Text (3583 words)

INTRODUCTION

The explosion in the use of electronic communication technology in all walks of life this pass decade has had a tremendous effect in our society and health care system is at the forefront of this. The Internet is one important example of how the application of electronic communication technology continues to advance health care. A survey done by harrisinteractive.com, the Internet arm of Harris market research and polling, found that eighty-six percent of Internet users said they were scanning the web for healthcare and disease-specific information-up from

71 percent in 1999 (McCarthy, 2000). The introduction of electronic technology devices in surgical procedures, the exchange of electronic information, and the ability of the hospitals to order supplies directly using the manufacturers' computer terminal and the timely delivery of the product(s), (Laudon, 2001), to mention just a few, attest to it's affect on the healthcare system as whole.

The bulk of obstacles that need to be overcome for the Internet to work in healthcare are not much different from the challenges faced by other industries seeking to harness its power (Tieman, 2000). Finally, healthcare managers must educate themselves and their organization regarding their duty to ensure that the privacy and security of individual identifiable healthcare information is maintained.

ON-GOING e-HEALTHCARE PROJECTS

Results of a Fall 1999 "Southeast Michigan Consumer Survey" by the MEDSTAT Group, Ann Arbor, Michigan, indicate that consumers' level of trust regarding health information found on the Internet varies by sponsor. Of the 600 consumers surveyed, those who search for health information online have the highest level of trust when the information is presented by a recognized organization (Herrmann, 2000). Most people also considered information trustworthy if the recommended site came from a physician. Many Internet sites benefit from this name recognition, for example, Healtheon/WebMD, mayohealth, ThriveOnline, drkoop.com, and WellMed. Healthcare organizations are also teaming up to create their own web site. MedUnite is a consortium of at least six major health plans; Aetna U.S Healthcare, CIGNA, WellPoint Health Systems, Oxford Health Plans, Foundation Health Systems and PacifiCare Health Systems.

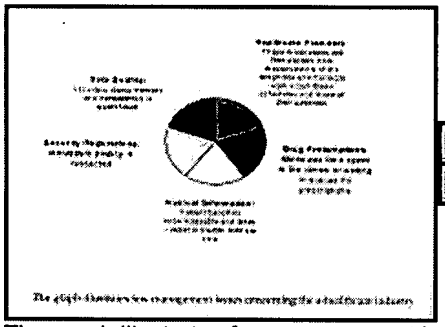
In United Kingdom, where socialized medicine is practiced, e-healthcare information is obtained from the National Health Services web site (NHSnet). In Europe as a whole, the European Unions are working on the way to decentralize information super highway that would be useful to all the counties that make up the Union.

TECHNOLOGY MANAGEMENT ISSUES

The following are graphical illustration of the management issues concerning e-healthcare and the discussions on the issues afterward.

1. EFFECT ON HEALTHCARE PROVIDERS:

The 2000 study, a follow up survey to the 1997 benchmark American MedicalAssociation (AMA) Study on Physicians' Use of the World Wide Web, reports that physician usage of the Web has nearly double from 20 percent from 20 percent in 1999; ninety-one percent send and receive e-mail, 84 percent access medical information sources, 80 percent collect travel information, 76 percent obtain product information, and 66 percent communicate with professional associates (Herrmann, 2000). With the introduction of electronic medical records (EMRs) developed by HealthPartners, a Minneapolis-based healthcare industry, medical records can reach almost anywhere, whether from an exam room PC, a laptop connected by a modem to a standard phone line, or a computer in a home office. In addition, if a primary care physician needs to send a patient record to a specialist, he or she can do so via the Internet or by instructing the specialist to log into a secure area of a central Web site called virtual private network (VPN), over the public shared infrastructure (Joch, 2000).



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The graph illustrates few management issues concerning the e-healthcare industry

Clinical decision support (CDS) system, a web based physician portal, which includes a clinical information system. CDS system component includes results review, electronic records, referral processing, secure

messaging, and order entry for prescriptions and test. Clinical decision support system can help physicians provide better care for patients and make their practices more efficient (Teich and Wrinn, 2000).

The collision of technology and medicine gave birth to FamilyMed.com, a comprehensive online resource specifically geared toward the specialty of family practice, the technology is call picture archiving and communications system (PACS), it uses an image server to exchange x-rays, CT scan, MRI and other medical images over a network. PAC system is now being used in most of the hospitals in American. FamilyMed.com produced by Medical Learning Company, Inc., Wellesley, MA, offers family physicians a variety of interactive tools and resources including case studies, multimedia programs and references, and links to more 30 journals. The site includes HeartLab, an online multimedia cardiac auscultation simulator. HeartLab allows physicians to listen to and diagnose unknown sounds from patients. Physicians would choose form a library of sounds on a simulated chest wall, reviews which maneuvers accentuate them, locate where they are best heard from patients and view a graphic representation of the sounds. The site also features virtual patient encounters, where physicians receive patient history, review of the systems, physical exam information, EKG strips and lab results allowing them to diagnose and recommend treatment. Electronic communication technology is becoming increasingly available in many ways to healthcare providers, with the introduction of telemedicine, which focuses on the provider aspects of healthcare telecommunications, especially medical images technology Physician can now care for a patient many distances away without seeing or knowing the patient and probably will never meet the patient. Data, medical images, physician notes on patients, and other types of data can be sent from one provider to another regardless of the distance between them. It is now possible to register a patient at one facility while the physician is at a different facility or even a different country and still be able to treat his or her patient depending on the type of illness the patient is suffering from.

In the U.S., more than 2.5 million people have cardiac devices implanted in their bodies. Minneapolisbased Medtronic introduced Medtronic.com, a computer-based patient management system that will transmit data gathered by various Medtronic implant devices, such as a pacemaker, to a secure file via VPN, accessible to physicians via the Internet. Patients linked to the system will be directly connected to their physicians, regardless of geographic location. The Medtronic.com system includes a programming device found in major cardiology clinics and academic centers. A complementary device, located in physician offices, will enable physicians to interrogate or program their patients' implanted devices from any remote location. Data would flow to the patient management system where it could be analyzed and reviewed by physicians (Her ir n ann, 2000). There is now a possibility of virtual surgery, where a patient can be diagnosed and operated on from far distant.

2. DRUG PRESCRIPTION: Five years ago the term "online pharmacy" was unfamiliar to most consumers. Mention it today among a group of people and chances are there will be few people among them that are using system or know somebody who is getting prescription online. Stemming from the success of the e-commerce model that had been widely used, the retail and other industries, entrepreneurs, including some chain drugstores, began to infuse large amounts of capital into the online pharmacy market. Drugstore.com, based in Bellevue, Washington, and PlanetRx, based in South San Francisco, are few examples of large online pharmacies. Jupiter Communications, a New York based media research firm, recently predicted that online prescription-drug spending will reach $966 million by 2003, representing 0.6 percent of the total retail prescription drug market. Using the Internet to safely and efficiently fill prescription was a welcome change to shopping in traditional bricks-and-mortar stores, which often involved long, waiting lines, and high prices (Kantor, 2000). Drug prescription can now be filled through the Internet without a patient seeing the doctor or pharmacist and can also find out when the prescription will be mailed or picked up. This method offers a number of advantages, especially to homebound patients and those taking long-term maintenance therapy, which could really benefit from the reduced prices offered through bulk purchases. Patients are not only able to fill their prescriptions online, but they can also obtain information about varieties of drugs via the Internet. "Ask Your Pharmacist", set up by Longs drugstores, a San Francisco based drug company fulfilled this dream (Cardinale, 2000).

Doctors can transmit orders to pharmacies and learn in real time whether what he prescribes is covered by an insurer's drug formulary (Chin, 2000). Considering some of the advantages that online pharmacies are bringing to the consumers, there are also many disadvantages associated with it as well. The most prominent among these is selling of both illegal drugs and prescription drugs from illegitimate sites, including vendors in foreign countries selling drugs that have not been approved in the U.S. However, the U.S Drug Enforcement Agency, Customs Services and others are making some progress against illegal site. There many sites online that a patient is required to pay a consultation fee of about $80.00 and your prescriptions will be on your way The fact this supposedly online doctor does not know if the patient is telling the truth about the reason for the medicine or not is a mind bottling to me.

In March 2001, the U.S. Customs Service shut down seven sites in Thailand that illegally sold prescription drugs to Americans over the Internet. U.S. officials also reportedly raided online pharmacies based in Thailand and seized 245 parcels ready for shipment to the U.S. and more than 2.5 million doses of drugs products that included Viagra, anabolic steroids, Valium, Tylenol with codeine, fen-pen, Xanaa, and Rohypnol (Kantor, 2000). New Jersey Attorney General's office sued two online pharmacists for illegally selling prescription drugs on the Internet. Experts estimate that there are at least 200 commercial online sites and another 200 illegal drug site. The safety of the online prescription drugs will depend not only on government effort but also from the public as well.

3. MEDICAL INFORMATION: Medical information is readily available online for the general public and an individual can access common web site like med line and pub med, which are provided to the public by the government through National Institute of Health (NIH). Recently, the NIH also provided an e-- biomed database that acts as a journal (Delamothe, 1999) and other sites are available for subscribers. According to a recent study commissioned by Healtheon/WebMD, fifty-five percent of Americans view the Internet information to the public as a reliable resource for healthcare information, while that number is just thirty percent for newspaper and twenty-eight percent for television.

Now, an individual can read about his or her illness via the Internet or through a question and answer live interactive section online with a physician and the necessary treatment that will be required, before even setting his or her foot in a clinic to see a doctor. Armed with this ready-made information, patients are becoming more knowledgeable about their health. Instant messaging, live interactive television, chart room or discussion board provide a future that is unimaginable.

4. THE SECURITY REGULATIONS: The ability to walk the fine line and at the same time be able to accomplish three issues concerning e-security, which are confidentiality of data, integrity of data, and availability of data. Confidentiality requires that medical data is not being disclosed to other, such as employers, making the identification of the patient possible. Integrity of data requires that unauthorized personnel are unable to alter medical records while changes made by others are tracked and recorded, and availability of data, which requires medical personnel must get access to patient files even during a massive power outage where generators may have to be used to guarantee availability of data.

With the explosion of the usage of electronic communication technology in the healthcare system, Internet, for example, poses new challenges to the protection of individual privacy that existing Fair Information Practices Principles are inadequate to address (Laudon and Laudon, 2001). In 1996, the government came out with a legislature proposal called Health Insurance, the Portability and Accountability Act (HIPAA). This code sets, national identifiers, security, and privacy. The goal is to reduce inefficiencies by making the healthcare system more electronic and standardizing the way healthcare entities exchange data and conduct business (Tabar, 2000). HIPAA law enacted both criminal and civil penalties for people or companies who use protected material that deals with privacy issues. For example, HIPAA's Administrative Simplification section calls for the creation of specific standards for electronic transactions, information with malicious intent or for personal or commercial gain. Even with this proposed legislature, individual privacy may not still be adequately protected.

5. DATA QUALITY: Data quality is very important issue in the healthcare system and e-healthcare industry for that matter. Data quality can be described as fitness for use (Tayi and Ballou). It actually means that the data are relevant to their intended uses and are of sufficient detail and quality with a high degree of accuracy, consistency and completeness (Lin and Chen, 2000).

Lin and Chen (2000) classified data quality into two dimensions, in what they called operational data and metadata. Operational data is the atomic data or summary information stored in data sets. Usually, the end users will inquire operational data to answer the health care question, while in the other way around, metadata is actually the data about the operational data. The end users must inquire from metadata to determine what types of information are available. Unlike operational data that is stored in data sets, metadata is stored in data dictionary or data repository. The bulk of obstacles that need to be overcome for Internet to work in e-healthcare is not different from the challenges faced by other industries seeking to become notice.

MANAGERIAL IMPLICATIONS

The concept of healthcare is the process whereby all information or orders are generated by the doctor or by the provider. It is also the concept of better management of information processes. It is this order, which are regarded

as legal and thus the capability to generate cash by the stakeholders to keep the system called healthcare running.

On this paper, we will use 5Cs framework or elements; content, context, community, customization, and care to the customer interface as they relate to e-- healthcare system to discuss the managerial implications.

CONTENT: This requires the ability to integrate meaningful messages or information generated by the physician to the patient through a support system (for example, the pharmacy), which can be digitally stored with the capability to retrieve when needed without compromising the data quality. Since sensitivity of the patient's record must be guard and protect, all possible efforts must be invested so that integrity and security of this vital information is not undermined.

The issues of loyalty come with accuracy of information, product quality or medical advice obtained online. Where the information come from and who is providing the information again generate loyalty. This process reduces paperwork transactions and thus alleviate some of the burdens face by an office management or the physician.

CONTEXT The quality of information on e-- healthcare system should not be compromised in any way or form. Not only that e-healthcare demands the highest quality data of information it must be readable to anybody that comes across it. It should be simplified so that it benefits an average patient who may not be familiar with medical jargons, while still maintaining the good quality. This can only be possible if the healthcare providers, the pharmacy, and the stakeholders are working together with the help of capable management information system. This will safeguard and prevent errors and at the same token protect the privacy of the patient's medical record.

COMMUNITY. The uniqueness of e-healthcare is not only the innovations that would free doctors from the constraints of the telephone and having to work around their schedules and those of their patients, it is also the ability for the patient to obtain whatever type of medical information, drug prescriptions, vitamins, medical products, and medical advice online and by the same token communicating with his or her doctor online anyway, anyplace. The ability for the patient to consult with the physician online through instant messages system or other forms of interactive communication.

CUSTOMIZATION: This will involve the ability for the patient's medical information to be digitally stored with the capability to retrieve any part of information anytime or anyplace, when the patient, the healthcare support system or the provider logs into the network. With the medical record stored in a data warehouse, patient's allergic statue can easily be checked, drug interactions and duplication of prescriptions would be discovered within seconds and thus avoid patient's potential injury or even death. This would also means that the manager or the provider armed with this error proof information system, can concentrate in the management of the office and a better care for the patient, instead spending so much fretting about being sued by the patient.

CARE: This is the most important issue of e-- healthcare. This issue here is the ability to delivery quality care irrespective of where it is obtained. The healthcare system stands to become one of the largest beneficiaries of the Internet technology. Last December, the release of To Err Is Human: Building a Safer Health System, a report by a blue-ribbon Committee on Quality of Health Care in America to the Institute of Medicine (IOM), chartered by the National Academy of Sciences, report estimates that between 44,000 and 98,000 patients die annually from medical mistakes (Baldwin, 2000). It is believe that a well-designed EMR eliminates errors due to illegible handwriting, an example of what the IOM calls "errors of execution". It also reduces inappropriate prescriptions, in report terms, "errors of plan". Take for example, practice partner, a software marketed by Physician Micro Systems, Seattle, the package checks prescriptions against a drug database for cross-drug interactions, against the patient's allergy lest and against the patient' past medication record to see if the same drug had been prescribed earlier with poor results (Balwin, 2000). A system like CDS, actually help the provider to become more effective and efficient. E-healthcare will actually improve patient care and can also reduce cost become more efficient and effective and the security of the patient record is protected in the process.

CONCLUSION

e-Healthcare system will become a win-win concept for not only the providers and the patients but also for the stakeholders. Malpractice suits will greatly reduced because of the built-in overview provided by these systems. The healthcare cost will greatly be reduced because of the reduction in paperwork, a section of the healthcare system that consume a great deal of revenue.

The information that healthcare industry produce is far more sensitive than most other information since they are personal and private information, but with the introduction of VPN, the security of this vital information could not still be assured because of trade offs, such as low cost, extreme reliability and extreme impliciteness.

Lastly, the reduction of paperwork transactions and time wasted on the queues or the clinics, the healthcare industry would become more accountable and efficient and at the same token reduced healthcare cost and save patients money and increase the profit margin for the stakeholders.

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Document 5 of 11

Building and Implementing Physician Practice Web Sites

Robert R Orford. **Mayo Clinic Proceedings**. Rochester:Feb 2002. Vol. 77, Iss. 2, p. 206 (1 pp.)

Full Text (300 words)

Building and Implementing Physician Practice Web Sites, by Michael A. Rothschild, 144 pp, with illus, $50, Chicago, Ill, American Medical Association (telephone: 800-621-8335), 2001, ISBN 1-57947-155-2

Type of Book: A softcover guide on use of the Internet in medical practice.

Scope of Book: This text provides a readable introduction to the development of physician practice Web sites for both novice and advanced Internet users.

Contents: Written by an ear, nose, and throat specialist who frequently speaks about Web site creation and online marketing of medical practices, this book is a helpful guide for physicians who are interested in creating their own Web site. Many physicians are now facile with computer use and e-mail but have not yet had the interest or opportunity to build a Web site to provide information concerning their practice to patients and prospective patients, medical content related to their area of medical expertise, and online communication with established patients. Using examples from his own practice, the author demonstrates how this can be done.

Strengths: Of particular value is the chapter entitled "Online Doctor-Patient Relationships and Cyber Medicine," in which the author clearly distinguishes between telemedicine and "tele-advice" and provides a template for such communication with patients, complete with a well-worded disclaimer. Another asset is a list of common errors in Web site creation (Appendix A) that physicians can use to ensure that their site optimally reflects their practice and professional image.

Deficiencies: Only general advice is provided concerning Web site design; those seeking detailed advice on Web authoring (XML, HTML, table creation, form incorporation, etc) are directed to other online and print resources on those topics.

Recommended Readership: Physicians with practice Web sites and those planning to create one.

Overall Grading: *****

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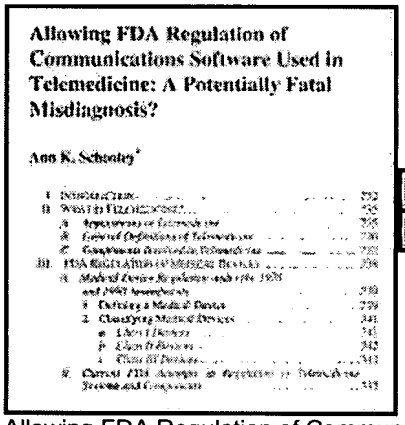
Allowing FDA regulation of communications software used in telemedicine: A potentially fatal misdiagnosis?

Ann K Schooley. **Federal Communications Law Journal**. Los Angeles:May 1998. Vol. 50, Iss. 3, p. 731-751 (21 pp.)

Abstract (Summary)
Communications technology is changing and improving the way that health care services are delivered to patients. Telemedicine, or the use of communications technology to provide medical care, allows doctors to treat patients in rural areas who otherwise would not have access to medical services. With the development and use of telemedicine, however, comes the burden to government regulation. The FDA is just beginning to assert its jurisdiction over telemedicine, seeking to regulate telemedicine systems are medical devices under 21 USC Section 231(h). Should the FDA strongly assert its jurisdiction, it has the ability to regulate the entire telemedicine systems, including all of the communications technology used in such systems. Potential regulation by the FDA poses serious problems for the telecommunications industry, and may have a deleterious effect in the research and use of telemedicine. The jurisdiction of the FDA to regulate communications technology used in telemedicine should be limited in order to encourage the widespread development of telemedicine.

Full Text (7538 words)


Allowing FDA Regulation of Communications Software Used in Telemedicine: A Potentially Fatal Misdiagnosis?

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I. INTRODUCTION

The way in which medicine is practiced changes almost daily thanks to emerging technologies. Today, "telemedicine" allows a physician to treat a patient who is halfway across the country-or even halfway around the world. Within the broad category of telemedicine, a host of subfields are emerging. Many medical specialties and

services are now developing and offering services via video conferencing and the use of communications technology. Teleradiology, teleimaging, telerobotics, teleoperation, telepsychiatry, telepresence, teleorthopedics, teledermatology, and telehealth1 are just some of the specialties using advanced telecommunications technology to provide medical care. Entire health care systems and providers are now using telemedicine. For example, Iowa has a virtual hospital and Singapore created a cyberspace hospital.2

Telemedicine promises to benefit everyone involved in the provision of medical care: doctors, patients, health care providers, hospitals, and insurers.3 For example, it benefits doctors by lowering the risk of malpractice since telemedicine allows quick and easy consultation with other doctors. Great potential exists for the use of telemedicine in training and educational contexts.4 In addition, doctors can greatly expand their potential patient base once they are no longer limited by geography. With health care professionals on both ends of a telemedicine transaction, telemedicine will improve treatment and provide better overall care, benefiting the patients.5 Patients in rural areas gain access to specialists and treatments that currently are only readily available in metropolitan areas.6 Telemedicine can also save time in delivering patient care,7 particularly in emergency situations.

Organizations that reimburse for health care expenses are perhaps the largest potential beneficiaries of telemedicine. The cost savings, especially long-term, are phenomenal. Some commentators estimate the cost of health care can be reduced by 36 billion dollars a year through the use of telemedicine.9 Telemedicine removes commuting and transportation costs of both doctor and patient, reduces duplication of tests and records, makes claim processing more efficient and cost effective, and reduces other administrative costs and delays.

While telemedicine promises great benefits, it also creates many societal, technological, and legal obstacles. Patients will have to be reeducated and given a chance to adjust to a new type of treatment. Many people may not feel comfortable being diagnosed by a doctor who is hundreds of miles away.10 The initial investment in equipment can also be substantial, with quoted start-up costs averaging $134,378 to $287,503,11 depending on how advanced the equipment is and its applications. Start-up costs can be reduced somewhat by using "off the shelf" systems rather than custommade systems.12 After the initial investment there are also fees for transmission and maintenance, which average anywhere from $18,573 to $80,068 annually.13 Equipment compatibility is a basic requirement, often difficult and expensive to achieve.

The legal issues involved in developing, operating, and maintaining a telemedicine system are endless. Maintaining the security of these systems, as well as protecting the patient's privacy, are major concerns that now are being addressed. Patients are unlikely to embrace telemedicine without assurances of confidentiality.14 Reimbursement by insurers is a major barrier to widespread use of telemedicine. Many insurers, including Medicare and Medicaid, will only reimburse for services provided with a face-to-face encounter between the doctor and patient.15 Because a large percentage of medical expenses are paid by insurers rather than the patients themselves, insurers' refusal to pay for telemedicine will sharply curtail its use. Doctors will be hesitant to use the new technology for fear of nonpayment.

Physician licensing and malpractice liability are also barriers to telemedicine.16 Because telemedicine does not recognize state boundaries, it creates the problem of a physician practicing in a state where she is not licensed17 or covered by malpractice insurance. Issues of jurisdiction and liability for mistransmission of data are also concerns that must be resolved prior to the widespread use of telemedicine. Governments are taking steps to address a number of these issues, mainly through legislation, and often on the state level.18

The complex problems and vast benefits created by telemedicine make it likely that the federal government will step in to regulate the field. If the federal government attempts to regulate telemedicine, the question will become: who will be in charge of creating the rules? The Federal Communications Commission (FCC or Commission), and the Food and Drug Administration (FDA) under the authority of the Food, Drug and Cosmetics Act (FDCA) are likely to be the key agencies involved since telemedicine involves both communications technology and medical technology. Of course numerous other agencies could assert jurisdiction, including, but not limited to: the Consumer Product Safety Commission, the Occupational Health and Safety Administration, and the Department of Health and Human Services.19

This Note discusses the potential jurisdiction of and attempts by one of these agencies, the FDA, to regulate telemedicine as a medical device.20 Part II looks at current definitions of telemedicine and the types of applications included in telemedicine. Part III discusses the definition of a medical device, the FDA's regulatory scheme for medical devices, and the FDA's current stance on regulation of telemedicine systems. Part IV examines issues raised by FDA regulation of telemedicine and the impact such regulation will have on telemedicine and related industries, particularly the communications industry.

II. WHAT IS TELEMEDICINE?

Half the battle in dealing with this new genre of patient care is defining telemedicine and determining what telemedicine encompasses. Many definitions are used, but most of the definitions tend to be rather broad. In formulating a general definition of telemedicine and in understanding the range of services telemedicine encompasses, it is helpful to look at some of the applications and their common factors.

A. Applications of Telemedicine

The potential applications of telemedicine are limitless. Everything from 911 emergency service21 to surgery performed by a doctor miles away22 to Web sites containing information on disease prevention" has been labeled "telemedicine." Some current applications include: sharing of patient information and records to save time and administrative costs;24 kiosks set up in urban areas allowing people access to basic healthcare;25 use in prisons to insure physician safety when treating inmates;26 use by the military to treat personnel at sea and in distant locations;27 home monitoring of the elderly and disabled;education and training;29 and providing ing of the elderly and disabled;28 education and training; and providing health care to residents of rural areas.30 Another application is computer diagnostic systems, often called medical expert systems (MES), which use one central computer to provide diagnostic information, calculations, and assessments to other remote users. However, all the potential uses have one common element: the use, in one way or another, of communications services and technology to transmit information from one place to another.31

B. General Definitions of Telemedicine

Creating a definition that would include all potential applications, or alternatively, determining which applications should be excluded is not easy. Overly broad definitions include any medical application that uses communications technology in any way, regardless of the small part such technology plays. For example, a phone conversation with a doctor is not what many people envision when thinking of telemedicine; yet, communications technology is used to help provide medical care. On the other hand, almost everyone would agree that a physical examination of a patient by a doctor miles away, using video conferencing and advanced technology is telemedicine. Yet determining where the line should be drawn-which applications should be considered telemedicine-is a difficult task.

The California Senate defined telemedicine as "the use of information technology to deliver medical services and information from one location to another."32 Telemedicine has also been defined as "the use of information and communications technologies to provide and support health care where distance separates the participants,"33 "medical diagnosis and treatment via telecommunications,"34 and the European Commission defines it as "rapid access to shared and remote medical expertise by means of telecommunications and information technologies, no matter where the patient or relevant information is located."35

The Joint Working Group on Telemedicine (Working Group), an interagency group headed by the Department of Health and Human Services, has created "working definitions" for telemedicine and telehealth.36 Telemedicine refers to health care services for individuals, while telehealth deals with general health care services. The Working Group's definition of telemedicine is:

The delivery and provision of health care and consultative services to individual patients and the transmission of information related to care, over distance, using telecommunications technologies, and incorporating the following activities:

I. Direct clinical, preventive, diagnostic, and therapeutic services and treatment, including procedures where a provider may be present with the patient, and clinical training and consultative clinical Grand Rounds, if used for decision making regarding the clinical care of a specific patient.

II. Consultative and follow-up services.

III. Remote monitoring, including the remote reading and interpretation of results of patient's procedures.

IV. Rehabilitative services.

V. Patient education provided in context of delivering health care to individuals.

The above definition includes a wide range of applications. It includes the type of services that many people think of as telemedicine, particularly video conferencing. But it also includes phone consultation between a doctor and patient as they discuss test results.

The Working Group's definition excludes certain significant applications such as numerous Web sites geared toward providing information to individuals; currently, these are numerous.38 In spite of the exclusion of applications such as Web sites, the Working Group's definition of telemedicine is one of the most specific and complete definitions and is the one used for purposes of this Note.

C. Components Involved in Telemedicine

It is important to consider what elements are included in telemedicine systems when trying to regulate them. By its nature, telemedicine involves multiple components and multiple parties. A minimum of three parties will be involved in any telemedicine transaction: the initiator of the transmission, the receiver of the transmission, and the communication service provider. Quite often more parties will be involved. The information may be transmitted to more than one doctor in more than one location. Additionally, because of the way in which phone service is currently provided, unless the transmission is within a small geographic area, several service providers are needed to complete the transmission of the data via modem. Each party to a telemedicine transaction will have its own equipment, both hardware and software, all of which could be a device for purposes of FDA regulation.

The number of components used in telemedicine, which could potentially be regulated by the FDA as medical devices, is tremendous. These include the hardware used by both the initiator and receiver: the monitors, video cameras, computers, wires and cables, keyboards, modems, printers, facsimile machines, and any other equipment used at their locations. In addition, the communications service provider uses hardware: the phone lines, cables, telephone poles, fiber optic cable, satellite equipment, switches, and other equipment which could face regulation as medical devices.

The software used by all the parties is another component in telemedicine systems and could potentially be regulated. The end users (both the initiator and receiver) of the transmission will have several types of software on their system. At a minimum, users must have some communications software in order to convert the data or images to digital form and then transmit them. The companies providing the communications service will also have their own software to direct the transmissions and deal with other routine and advanced functions. As part of a telemedicine system, all of these components are potentially subject to regulation as medical devices by the FDA.39

III. FDA REGULATION OF MEDICAL DEVICES

Prior to 1976, the FDCA allowed the FDA to regulate drugs, but it was not able to regulate medical devices directly.40 If the FDA wanted to regulate a medical device it had to first classify it as a drug, and then the device could be regulated according to the regulations applicable to drugs.41 This burdensome method of regulating medical devices ended in 1976 with the passage of the Medical Device Amendments of 1976,42 which gave the FDA authority to regulate medical devices directly. The Safe Medical Devices Act of 199043 supplemented the 1976 Amendments and attempted to create improved, comprehensive regulation of medical devices designed to promote public health and safety.

A. Medical Device Regulation under the 1976 and 1990

Amendments44

The 1976 and 1990 Amendments to the FDCA were intended to allow FDA jurisdiction over medical devices to ensure that the device itself and its use did not pose a risk to the safety or health of the public. The FDA asserted its jurisdiction and created extensive regulations applicable to medical devices. Unfortunately, the regulatory scheme proved to be overly burdensome. In addition to preventing the distribution and use of unsafe medical devices, the delays in reviewing the required application documentation prevented the use and distribution of many safe and helpful medical devices.

Defining a Medical Device

The FDCA defines a device at 21 U.S.C. 321(h) as: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is

(1) recognized in the official National Formulary, or in the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and

which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Only one of the three elements listed above must be present to classify an object as a medical device. This definition is extremely broad and can be interpreted to cover a vast array of products.46 In fact, this definition gives the FDA jurisdiction over almost any device or product used in the medical field.

The FDA has found many products that are not widely regarded as devices intended for medical purposes to be medical devices under 321 (h). Such products include an E-meter (a polygraph-like device used by the Church of Scientology allegedly to cure disease), a vinyl-covered bed with speakers mounted on the sides,48 and phonograph records.49 The FDA has also regulated devices that never have any direct contact with patients, such as laboratory specimen collection containers50 and surgical instrument sterilizers.51

The courts found that in determining whether a device qualifies as a medical device for regulatory purposes, first the court "must give broad deference to the FDA's reasonable interpretation of the statutory scheme that it is entrusted to administer."52 Additionally, no direct contact with patients was necessary for an item to be a device. "Indeed, even device 'accessories' and 'components' intended for use in devices standing alone, constitute devices."53 The court stated:

[T]he Supreme Court noted that Congress intended products "such as electric belts, quack diagnostic scales, and therapeutic lamps, as well as bathroom weight scales, shoulder braces, air conditioning units, and crutches" to be devices. The inclusiveness of such items as devices reflects Congress' clear intent to characterize "basic aids used in the routine operation of a hospital . . ." as devices.54

One Senator lamented "[t]he language [of the bill] is broad enough to cover any device of which the Food and Drug Bureau of the Agricultural Department chooses to take jurisdiction."55 The courts have generally given broad discretion to decisions of the FDA as to the devices subject to regulation under (sec) 321(h).

Most medical devices fall under (sec) 321(h)(2) as "intended for use in the diagnosis... cure, mitigation, treatment, or prevention of disease .... .56 Almost any of the components of a telemedicine system could fall under this provision. After all, the purpose of telemedicine is to allow for the treatment, diagnosis, or prevention of disease using communications services to connect the doctor and patient. It is not much of a jump for the FDA to attempt to regulate telemedicine systems either as a whole or to regulate parts of such systems. The broad definition of a medical device in 321(h) would allow regulation of virtually any part of a telemedicine system, including communications equipment and services.

2. Classifying Medical Devices

Once an item is found to be a device under 321(h), it must be classified. The FDA places devices into one of three categories based upon the level of risk they create to the health and safety of both the patients and health care providers.57 Class I is the classification applicable to devices creating the lowest risk,58 therefore subject to the least regulation.59 The general controls for Class I devices are applicable to all devices regardless of their classification.60 Devices placed in Class II create more risk than those in Class I and are subject to additional controls to ensure their safety.61 Most medical devices are placed in Class II.62 Class III devices pose the greatest risk, requiring the most scrutiny, including premarket approval by the FDA.63 All new devices that are not

substantially equivalent to a device existing prior to the 1976 amendments are automatically placed into Class III.64

a. Class I Devices

The Class I general controls are applicable to all medical devices. They include requirements placed on adulterated devices;65 requirements for misbranded devices;66 registration;67 inspection of premises requirements;68 listing of devices manufactured;69 premarketing notification;70 notification of risk to purchasers and users of the device;71 reporting of adverse effects of the device;72 and good manufacturing practice requirements.73

While this is a very simplified glance at the Class I requirements, the effect of the above requirements on manufacturers of telemedicine devices or systems can still be seen. Particularly, the requirement that notice be given to the FDA prior to marketing of such systems or certain components of the system intended for use in telemedicine will deter companies from developing and marketing such devices. Additionally, compliance with the good manufacturing requirements and premises inspection requirements may call for such a change in the way businesses manufacture that it will not be economically feasible for them to comply. Rather, businesses will simply not market their components and systems for use in a telemedicine context.

b. Class II Devices

Class II devices are subject to additional regulations beyond the general controls for Class I devices. The special controls or performance standards for Class II devices can include "promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, ... recommendations, and other appropriate actions as the Secretary deems necessary to provide [reasonable] assurance [of the safety and effectiveness of the device]."74 Rather than being generally applicable to all Class II devices, these special controls are often imposed on a device-by-device basis.75 Due to the large number of devices in Class II,76 the process of issuing standards for all Class II devices is daunting. Administrative regulations for classifying devices further hinder the process.77 Consequently, few performance standards for Class II devices have been issued.78 This in practice eliminates the distinction between Class I and Class II devices because until Class II standards are created, compliance with the general Class I standards is all that is required.79

c. Class III Devices

Premarket approval (PMA) is required for all Class III devices. Premarket approval requires the manufacturer to file an application showing that the device is safe and effective;80 describing the components and properties of the device;81 the methods used in manufacturing and packaging the device;82 and the proposed labeling for the device.83 Additionally, PMA allows only that particular applicant to market the device.84 If another manufacturer desires to market its own version of the same device, it must go through the PMA process anew for its version of the device.85 The FDA is required to act on applications for PMA within 180 days of receipt.86 However, in practice the process takes approximately one year.87

The long delay in ovtaining PMA for telemedicine systems and/or their components will severly hinder the development and application of telemedicine. As rapdily as communications technology changes, a oneyear delay in receiving PMA is equivalent ot an eternity. Manufacturers cannot sell any Class III device or system until the device has received PMA. If forced to wait a year or longer for approval, the technology that the approved system was based on may become obsolete and uneconomical to produce. Without an economic incentive to produce these systems and components, manufacturers will withdraw from the market, to the detriment of telemedicine.

B. Current FDA Attempts at Regulation of Telemedicine Systems and Components

The FDA has provided no clear guidance regarding the role it will take in the regulation of telemedicine systems. Thus far the FDA has made no attempts to regulate telemedicine systems as a whole, and has done relatively little to regulate the individual components of such systems, beyond regulating "traditional" medical devices used in telemedicine.88 The lack of guidance from the FDA poses a huge problem for those developing such systems, for those manufacturing components of the systems, and for those health care providers purchasing a system-only to later find out it does not comply with newly created FDA regulations. The problem of compliance with FDA regulations may also arise because many of the systems used today are "adaptations of existing teleconferencing

or desk top computer systems which were originally designed for purposes other than health care delivery."89 It is unlikely that a computer manufacturer will be willing to change its manufacturing process and procedures to comply with FDA regulation of a manufacturer's system when the system was not intended for medical use and can be marketed for numerous other profitable applications.

Despite the problems of regulating telemedicine, it is unlikely that the FDA will simply decline to assert jurisdiction over telemedicine. The Telemedicine Report to Congress states "[w]ith respect to telemedicine, the FDA is responsible for ensuring the safety and effectiveness of telemedicine devices marketed in the United States."90 The FDA is beginning to take steps to regulate telemedicine. It has already started to regulate hardware, specifically teleradiology systems and medical imaging systems.91 What, if any, regulation other hardware will be subject to remains unclear.92

A key component or area that the FDA is beginning to regulate is software used in telemedicine systems. However, exactly what is regulated and to what extent is unclear. Several draft policies have been issued, but they do not have the force of regulations.93 The policies have recognized some software as medical devices.94 Other software is currently regulated on an ad hoc basis.95

If the FDA uses the traditional approach to medical device regulation, it has the option of simply labeling the software as a general purpose device; as such the software is not subject to regulation.96 In an FDA software policy workshop, several examples falling into this category of general purpose devices included programs controlling computer hardware that were not specifically designed for medical applications, as well as "offthe-shelf" software such as word processing programs and database programs.97 The communications software used in most telemedicine systems was not designed for a medical application and would seem to fall into the category of general-purpose devices.

Alternatively, it has been suggested that if the software is an accessory, used in conjunction with another device regulated by the FDA as a medical device, the software could be subject to the same level of regulation as the associated device.98 This seems to indicate that communications software used as part of a telemedicine system could be subject to FDA regulation if it is found to be an accessory to another regulated device. For example, communications software could be viewed as an accessory to traditionally regulated devices, such as radiology equipment. The software could enhance the equipment by allowing the images to be transmitted via wire lines to a remote physician. Thus, the software becomes an accessory to the radiology equipment, and the FDA can regulate the communications software.

In its Guidance for the Content and Review of 510(K) Notifications for Picture Archiving and Communications Systems (PACS) and Related Devices (Guidance for PACS), the FDA, through the Center for Devices and Radiological Health, seems to include communications software as a medical device subject to regulation. The document begins by stating "[t]his guidance is applicable to picture archiving and communications systems (PACS). PACS are systems which are intended to provide transmission, storage and viewing facilities for medical diagnostic images at distributed locations."99 In essence, PACS are the "linchpin" of many telemedicine systems,100 and the Guidance for PACS seems to indicate that PACS systems can and will be regulated as medical devices.

The Guidance for PACS then states that it is also applicable to related devices that perform functions provided by PACS, including image communications equipment, both networks and interfaces.101 This would give the FDA jurisdiction to regulate not only communications software but communications networks as well. This is a frightening proposition for those developing and maintaining networks and providing communications services. Confusing the issue further, the document goes on to state:

The guidance does not apply to general purpose devices if they are not specifically indicated or promoted for use in conjunction with medical images. These products are not considered to be medical devices and premarket notifications are not required. Examples of such devices include general purpose communications systems, data storage media and software. However, if general purpose devices are indicated or promoted for medical use, a 510 (k) must be submitted. Also, if they are sold as a PACS component, they must be described in the 510 (k) for the system.102

The applicable level of FDA regulation seems to depend on whether manufacturers indicate or promote the device for medical use. If they promote it for medical use, then they are subject to the entire gambit of FDA regulation. If they simply allow their device to be used as a component but do not promote it for medical use, then

the device only needs to be described in the required documentation for the PACS system, rather than being subject to its own separate review. To subject two different manufacturers making an essentially identical product, ultimately used in the same manner in a telemedicine system, to different levels of regulation based on how they promote their product makes little sense.

Other approaches have been suggested for the regulation of devices containing software, such as establishing levels of concern and regulating based upon the level of concern or risk the device creates, rather than the traditional class system. The FDA drafted such a proposal, and the proposal indicated that some level of scrutiny would be applied to software regardless of whether it was general purpose software or software designed for medical uses.l03

So far, the FDA has issued no consistent, clearly articulated regulations or policies regarding communications software used in telemedicine systems. The documents currently available provide little assistance to those manufacturing or developing telemedicine systems or the software for such systems. Despite the lack of specific guidance from the FDA, it appears that the FDA has adopted an approach of regulating the individual telemedicine system components rather than regulating the systems as single units or single medical devices. This has important implications for those involved in creating and developing both the components of such systems and the systems themselves.

IV. APPROACHES TO FDA REGULATIONS OF TELEMEDICINE AND THEIR IMPLICATIONS

When evaluating approaches to the regulation of communications hardware and software used in telemedicine and their implications, it is important to remember exactly what parts or components are involved in a telemedicine system. The actual computer hardware and software used to run the systems at the health care provider's office; the communications software used by the health care provider; the modems; the video cameras; the monitors; the specialized medical equipment that is connected to the system; the communications software used by the communications service provider (such as AT&T, MCI, and Ameritech); the hardware (copper lines, fiber-optic cable, satellites, etc.) used by the service provider to transmit the data; and the method in which the information is sent are each potentially subject to regulation under the current, broad definition of a medical device.

The FDA has several options in attempting to regulate telemedicine systems and components. One is to regulate the systems as a whole or as a single medical device. But to set out one regulatory scheme or approach applicable to all the different components within a system is a complex, virtually impossible task. Some components of a system pose a greater risk to the safety and health of patients and users than others. Different systems pose varying levels of risk depending on their applications. Regulations appropriate for medical software used for telemedicine may not be appropriate for the cables transmitting the information to its destination.

Regulating systems as a whole would require the FDA to regulate not only the communications software and hardware, but also the equipment used to transmit the data and the manner in which the data is transmitted. Any regulation would cover the communications service provider's hardware and software as well as the individual communications software used by the health care provider. It is questionable whether it is desirable for the FDA to become involved in regulating communications in any aspect, and the communications companies are unlikely to agree to stricter standards in their hardware, software, and procedures-especially if it increases their costs. Rather than incur additional costs related to FDA compliance, manufacturers will simply market their communications software and hardware for other more profitable applications, and withdraw from the telemedicine market.

Further, any change in the system could require new approval for the entire system.104 Each time a device is changed, no matter how minor the change, FDA approval is required.105 The use of new cable or wire could place the system behind all of the other devices awaiting FDA approval. An already backlogged FDA is unlikely to provide quick approval, even for minor changes.106 All of these factors lead to the conclusion that FDA regulation of telemedicine systems as a whole is not desirable or feasible. Wisely, the FDA does not appear to be aggressively pursuing this approach.

A second approach, similar to the current stance taken by the FDA, is to individually regulate each component of telemedicine systems. This approach addresses many of the concerns about regulating the systems as single

medical devices. Regulation on a component-by-component basis allows consideration of the different levels of risk created by the different components, and allows for varying levels of regulation based on the level of risk.

This also avoids new FDA approval for the entire system each time one component is changed. Approval can be sought only for the component that is changed. The effect of the change on the entire system can be documented and submitted, but there is no need to redocument the entire system for new FDA approval.

The biggest advantage of regulating the components of the system individually is the possibility of the FDA exempting certain portions of the systems from FDA regulation. As discussed previously, FDA regulation of the communications industry is troublesome. This will allow exemption of communications hardware and software, particularly PACS. The FDA can continue to regulate those components that are truly medical devices and are used directly in the diagnostic process. For example, x-ray systems, CAT Scan systems, and heart monitors would still be regulated by the FDA. However, those components dealing with other functions, such as communications, data processing, and management, could be excluded from FDA regulation. Freeing communications software providers and developers from potential FDA regulation would encourage their active participation in telemedicine projects and would be a huge boost to the development of telemedicine. Communications service providers are much more likely to support telemedicine if their involvement does not impose additional regulations and costs.

Communications providers will continue to be subject to the regulations imposed by other regulatory agencies, but will not have the additional burden of FDA regulation. Due to the crucial nature of the data being transmitted, higher standards may be desirable. However, if such standards cause the service providers to withdraw from the market, then the benefits of telemedicine are lost. Any risk of mistransmission or a total loss of data can be distributed between the parties involved through individual contracts allocating the risk. By allocating the risk via contract, each party will know what their potential liability is and will be able to act accordingly.

Although regulation on a component-by-component basis is more desirable than regulation of entire telemedicine systems, a component-bycomponent approach will work only if the FDA acts reasonably with regard to the components of telemedicine systems over which it attempts to assert jurisdiction. While initially regulating only "traditional" medical devices, the FDA is increasingly moving toward broader assertions of jurisdiction. As it attempts to regulate more and more aspects of telemedicine systems and computer software, more problems will arise.

Software manufacturers or developers are in an especially problematic position to deal with FDA regulation. With each new version of the software, new FDA approval would be necessary. Every change to eliminate a bug in the program could potentially require additional FDA approval. Requiring essentially continual FDA approval for every change in the software "`will have a chilling effect on the evolution of software technology."'107 Even if approval is granted in a mere six to seven months,108 well within the current time frame of one year, the software will be out of date upon its approval. Consequently, telemedicine systems will be forced to use outdated software, often with known and correctable errors, due to lack of FDA approval of the updated version.

This dilemma and its results can be seen in the context of blood bank software. Once the FDA asserted jurisdiction over blood bank software and promulgated regulations, the number of developers and manufacturers immediately began to decrease. "`Some software developers have already with drawn [sic] from the blood bank market. They feel it's not that large of a market for them, and feel that software changes are sort of an evolutionary thing, and that any software upgrade would require a resubmision."'109

A similar result is likely to occur in the communications software industry. As the FDA begins to assert jurisdiction over communications software used in telemedicine, developers of such software will leave the market rather than incur the additional costs of compliance with FDA regulation. This is especially true since communications software has a multitude of nonmedical applications that do not require compliance with burdensome regulations.

While it is not apparent that the FDA needs to regulate communications software to ensure the safety and effectiveness of telemedicine systems, if it is unwilling to decline jurisdiction, it must take a different approach to the regulation of communications software. New guidelines specifically for software must be created. Rather than regulate software through the traditional scheme now in place for medical devices, software could be dealt with separately on an expedited basis. Thus the rapid changes and limited life of software could be taken into account, allowing telemedicine systems to use updated and current software without awaiting slow, traditional FDA approval.

V. CONCLUSION

Telemedicine systems and their components fall under the broad definition of medical devices set out in 21 U.S.C. 321(h). Technically, there is nothing to prohibit the FDA from asserting its jurisdiction over telemedicine systems or components. Already the FDA has begun to regulate some components of telemedicine systems and is beginning to regulate PACS and other related communications software.

The current lack of clear guidance on the regulation of communications software and PACS will hinder the development and use of telemedicine. Clearer policies and guidance on the FDA's approach to telemedicine systems are essential. Without them, systems manufacturers and developers will be wary of entering the market, not knowing whether they are in compliance, and whether they will be subject to penalties for noncompliance.

As the FDA attempts to regulate telemedicine, a decision has to be made whether to regulate the systems as a whole or as individual components. Although the FDA appears to have adopted a reasonable, component-by-component approach, it remains to be seen how it will implement that approach. The FDA's actions on this point will dramatically affect the future of telemedicine.

If the FDA asserts jurisdiction over all components in telemedicine systems, including communications hardware and software, the results will be disastrous. As communications services are finally becoming deregulated, the last thing the providers want is to comply with additional FDA regulations, especially since telemedicine is likely to be a small part of their overall market. Without communications services, telemedicine is at a standstill. Maintaining an appropriate balance between regulation to ensure safety of telemedicine systems and deregulation of the communications industry is essential to the future success of telemedicine.

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12. Telemedicine systems can be custom-made by manufacturers and tailored to suit a specific medical practice or need, or they can be created "off the shelf" by literally going to vendors and purchasing separate components intended for use in a variety of applications and then building the system from the various components. 13. TELEMEDICINE REPORT, supra note 11, pt. II.G.

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[Footnote]
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[Footnote]
44. The following is a very basic, simplified overview of FDA regulation of medical devices. It is not meant to be comprehensive, but merely to give a quick glance at some of the main provisions. 45. 21 U.S.C. 321(h).
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62. Nguyen, supra note 57, at 1206. "Class II devices include syringes, bone plates, hearing aids, resuscitators, and electrocardiograph electrodes." Id.
63. 21 U.S.C. 360c(a)(1)(C); Nguyen, supra note 57, at 1206. Examples of Class III devices are "pacemakers, intra-uterine contraceptive devices (IUDs), artificial hearts, and artificial joints." Id. 64. 21 U.S.C. 360c(f)(1). 65. Id. 351. 66. Id. 352. 67. Id. 360(b).

[Footnote]
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79. Id. 80. Id. (sec) 360e(c)(1)(B). 82. Id. (sec) 360e(c)(1)(C). 83. Id. (sec) 360e(c)(1)(F). 84. Kessler, supra note 76, at 359. 85. Id. There are limited exception to this rule; most significantly, manufacturers are allowed to use data from other PMA applications once it has been accepted by the medical community. 86. 21 U.S.C. (sec) 360e(d)(1)(A). 87. Kessler, supra note 76, at 359.

[Footnote]

88. These "traditional" medical devices include those devices which are merely hooked into the telemedicine system or

used during the telemedicine consult, but would also be used in a regular face-to-face consultation. Some such devices are: stethoscopes, an EKG machines, heart monitors, and x-ray machines. 89. TELEMEDICINE REPORT, supra note 11, pt. V.A. 90. Id.
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98. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FDA, GUIDANCE FOR THE CONTENT AND REVIEW OF S IO(K) NOTIFICATIONS FOR PICTURE ARCHIVING AND COMMUNICATIONS SYSTEMS (PACS) AND RELATED DEVICES (visited Jan. 30, 1998) <http://www.fda.gov/cdrh/ode/odeot4l6.html> [hereinafter GUIDANCE FOR PACS]. 99. Id.
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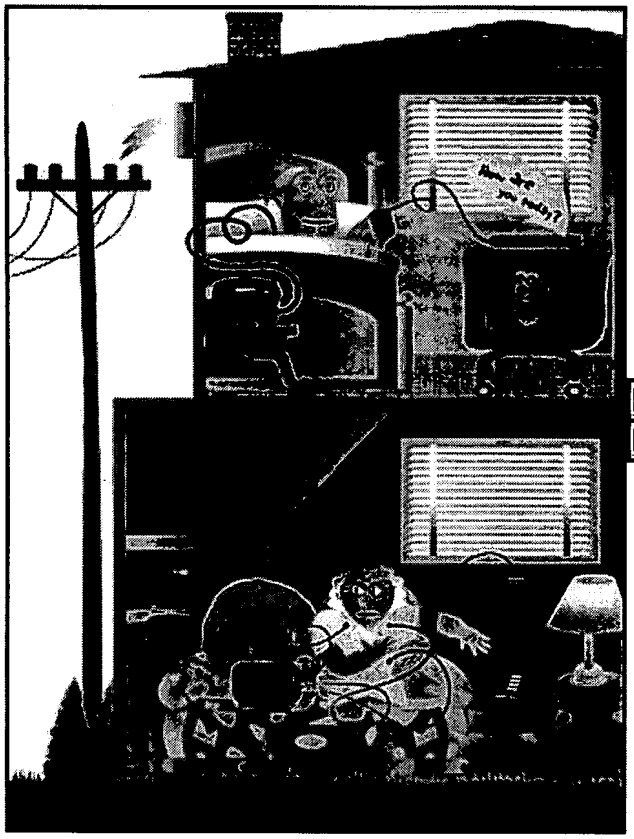
Home is where the heart monitor is
Carol Lewis. **FDA Consumer**. Rockville:May/Jun 2001. Vol. 35, Iss. 3, p. 10-5 (5 pp.)

Abstract (Summary)
Medical devices, products and technologies are converging to revolutionize home- and self-care health system in the US, making it possible for people to play a greater role in maintaining their own health. The primary need for today's home-care population is more frequent and convenient monitoring of chronic diseases and conditions.

Full Text (2387 words)



Home Is Where the Heart Monitor Is

Medical devices, products and technologies are converging to revolutionize home- and self-care health systems in the United States, making it possible for people to play a greater role in maintaining their own health.

These systems are geared toward a prevention-oriented, consumer-driven model for health care that includes innovations such as "smart devices" that can "think" for themselves, customized wearable devices, electronic patient records, and wireless Internet-linked systems-all expected to deliver convenient, user-friendly, intelligent health care in the home.

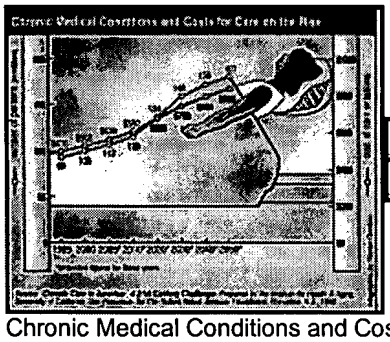
For consumers, this could mean convenience in time and travel and reduced health-care costs, and-it is hoped-result in home-care systems that teach people to monitor themselves with gizmos that give timely warnings of

illness so that they can turn to their physicians early-when intervention will do the most good. For doctors, it could mean more efficient-and effectivehealth care driven by patients who take greater responsibility for their own health.

William Herman, director of the division of physical sciences in the Food and Drug Administration's Center for Devices and Radiological Health (CDRH), which regulates medical devices, calls home-care systems "the fastest growing segment of the medical device industry."

'If You Build It, They Will Come'

The list of planned and imagined medical devices reads like a work of science fiction. For example, imagine a toothbrush with a biosensing chip that checks your blood sugar and bacteria levels while you're brushing your teeth. Optimally, the brush would come with a holder that would transmit information to a database containing the person's medical file. Other devices on the drawing board include computerized eyeglasses with a tiny embedded display that can help those who wear them to remember people and things, and skin surface mapping, a new imaging technology that can collect images of the skin surface over time and would enable people predisposed to melanoma to detect malignant moles as soon as they begin to develop.



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Chronic Medical Conditions and Costs for Care on the Rise

Also in the future, hand-held biosensors resembling the technological gadgets wielded by "Bones" on the TV series Star Trek could eliminate the need for maintaining large laboratories. A "smart" bandage could be made of fiber that could detect bacteria or virus in a wound, and tell the wearer if treatment with antibiotics is warranted and which to use. Using a wide range of advanced technologies such as wireless electronics and digital processing, heart monitors that can be connected to personal computers could make it convenient for people to track their own heart rates and other vital information at home and then transmit it to their health-care providers.

The Defense Advanced Research Projects Agency, within the U.S. Department of Defense, has developed a wearable system called the "smart T-shirt," which successfully monitored the vital signs of climbers on a recent expedition to Mount Everest. Another type of device that allows people with disabilities to operate machines and perform routine tasks is a hands-free instrument that is controlled by small muscle movements, such as a blink of an eye (electromyography), and brain activity (electroencephalography). Other devices include those controlled by tracking eye movements or by speech recognition technology. Devices that offer this kind of assistance show promise for individuals with spinal cord injuries or other nervous system disorders resulting in paralysis.

Products well along in the development pipeline are about to make possible dramatically improved pacemakers, cochlear implants (for hearing), and medicine delivery systems. Some of these devices will incorporate the most advanced product design and manufacturing on a molecular scale (nanotechnology) and other state-of-the-art technologies, such as microprocessors and miniaturization. The ability to bring these kinds of tools into the home adds a dimension of health care that people never had access to in the past.

"Do we know what's going to work?" asks Gilbert Devey, program director for biomedical engineering at the National Science Foundation. "Not yet," he says, "but there are ample precedents for these types of technologies. The focus now is on increasing the level of technological literacy for consumers."

Shifting Responsibilities

With some 76 million Americans born between 1946 and 1964 heading toward retirement, emerging technologies

likely will help care for this aging babyboomer generation. Technology is already being used to help keep tens of millions of older people in assisted living situations a lot safer.

At 9:30 a.m. on a recent Monday, nurse Linda McRae asks her patient: "How's your appetite? What about your bowels? Are you coughing up anything?" The questions sound routine; however, the physical exam is not. Elwin Geyer, a 69-year-old chronic lung disease patient, is at home--some 25 miles away from McRae. But from the video room in Kaiser Permanente's Sacramento, Calif., home health-care facility, the two are virtually connected by the flip of a switch, and McRae can examine Geyer long-distance, thanks to telemedicine.

Telemedicine connections like this one bring high-resolution images and audio through not much more than a telephone line and a computer monitor. A telemedicine device installed in the home allows a nurse to complete an exam without the person ever having to leave the house.

In February 2000, the FDA cleared for marketing one of the latest telemedicine devices that includes a blood pressure cuff, stethoscope, and thermometer, as well as a television monitor and camera. The medical information that Geyer's wife, Jean, helps obtain by maneuvering the stethoscope over her husband's chest and back is transmitted from the devices directly to McRae. New, cheaper devices connecting telephones and televisions to the Web have the potential to expand this technology even further.

"Telemedicine is simply a steppingstone to a more sophisticated home health-care future," says Steve Warren, Ph.D., assistant professor of electrical engineering at Kansas State University. It's a steppingstone that McRae says adds an element of reality to her job as a home-health nurse by allowing her to promptly see what's troubling her patient. She says that systems like the one used by Geyer "give patients confidence and reassurance that we can do more than just talk to them by phone."

But as information technology becomes a more robust resource for people and their health-care providers, the link to home- and self-care products will raise issues such as liability, privacy, financing, and most important, the safety and effectiveness of the products.

The National Association for Home Care in Washington, D.C., conducted several clinical trials of home-distance monitoring of blood glucose levels by computer and found improved outcomes in diabetes care. Similarly, trials of home-distance monitoring of blood pressures showed enhanced efficiency. But failure to improve outcomes of high-risk pregnancies through home-distance monitoring illustrates the difficulties in managing certain clinical applications in the home environment, and the need for further research and regulatory controls.

New FDA policies, guidelines, and regulations may be needed, says the FDA's Herman, especially once it's clear how the Internet will change device regulation. These guidance documents will require special consideration of the capabilities and limitations of people using the devices at home as well as in different types of environments.

User Issues-A Major Concern

Given the newness of various technologies and known problems with some home-use devices, CDRH is going to be skeptical of new medical technologies that are long on promise to consumers, Herman says. As technological developments become more complicated, so do the requirements for their design to ensure that they can be used safely and effectively in the home.

"Human factors" is the science of interactions between people and technology, and involves designing a device with the users' abilities, limitations, and operating environments in mind. Ron Kaye, a human factors specialist in CDRH, says that the possibility of user errors (unintentional mistakes) always is of particular concern.

Medical device design problems can lead to errors when they don't consider that consumers can become easily confused using devices in the home. Distractions, such as children or other family members, variations in lighting and noise levels, and the demands of using the device exceeding the user's capabilities, all can contribute. A patient receiving oxygen, for example, died when a pressure hose loosened from the unit. The alarm was not loud enough to be heard over the drone of the device. Dropping a device or using it in changing temperatures or high humidity (such as a bathroom or shower) also may affect its performance. Kaye says other problems, such as not following procedures precisely or relying on the device too heavily, also are concerns.

"These risky behaviors can involve lifestyle changes, such as changes in diet or physical activity, or less attention to monitoring their health condition due to over-reliance on the device," says Kaye. And, usually once the user becomes accustomed to a device, failing to follow maintenance and calibration procedures, taking shortcuts when a specific technique is critical, or failing to communicate with health-care professionals as often as they should, also could lead to trouble.

The critical question, Kaye says, is whether consumers will be able to use new medical technology without unintentionally making errors that could compromise their health.

The ability of patients to operate a medical device, for example, can depend on medical training and experience, language barriers, literacy, memory, learning ability, dexterity, vision, and hearing. Difficulties using certain devices can be caused by advanced age, medications, or the actual medical condition that requires use of a product. The focus of most of CDRH's guidances will be on ensuring that users are able to safely operate and maintain the device-anything they would need to know about, such as controls, displays, software, labeling, and instructions.

Although new devices give people increasing control and a feeling of security when managing their health, users must remember to keep in regular contact with their health-care providers, Kaye says.

No Mistakes

Stephen B. Kaufman, a pioneer in home-care technology from Deerfield, Ill., supports device technology that has "simple prompts" and "no possibility of mistakes." He says, "There are just too many opportunities to make bad mistakes." For this reason, CDRH has provided human factors guidance to manufacturers on device design that will reduce the likelihood of user error. This guidance document, titled "Medical Device Use Safety: Incorporating Human Factors Engineering Into Risk Management," can be found on CDRH's Web site at www fda.gov/cdrh/humfac/ 1497.pdf.

"Design controls are another new regulatory tool for us that have a lot of potential to avoid use errors and other device quality problems," says Stewart Crumpler, a regulatory operations officer in CDRH. Design controls are a system of checks and balances that increase the likelihood that a device is designed, manufactured, used, and maintained properly, and that the device is appropriate for its intended use. Design controls are the part of a quality system that requires manufacturers to consider both human factors and the intended use environment during device design. The controls, Crumpler says, are intended to "build quality into the device."

Another factor contributing to the increase in user errors is the difficulty that consumers have understanding instructions provided with devices. Most are written for health-care professionals. CDRH has prepared guidance for manufacturers of home-use devices to help them plan and write their manuals for consumer use.

"One of the biggest problems we're finding," adds Herman, "is the inability of systems to be used by people who have not been trained." Because of this, CDRH's guidances also will focus on patient education and training, proper technical standards for manufacturers, and safety issues that new technologies may generate.

A New Paradigm for Health Care Today, what could be characterized as a return to home health care has much to do with the emergence of the Internet as a conduit of health information to patients. Those who remember huge mainframe computers can appreciate today's technology and the exponential advances in the compilation and distribution of information.

"For some time now, the technology forecasts of CDRH's office of science and technology have projected home- and self-care devices as a high probability area for dramatic growth," says Herman. Other forecasts, he says, are now mirroring those CDRH expectations. This unfolding wing of modern medicine means that 21st century home- and self-care devices could soon revolutionize health-care delivery systems in the United States. And when these potential technological marvels are ready for the market, some may lead to products that we may wonder how we lived without.

[Sidebar]
For more information on home heath-care issues, contact:

[Sidebar]
American Association for Home Care
www.aahomecare.org
703-836-6263
Represents about 1,000 home-care providers, equipment suppliers and service providers.

[Sidebar]
American Nurses Association
www. ana.org
1-800-274-4ANA (1-800-274-4262)
Represents 2.6 million registered nurses. Has developed guidelines on use of telehealth.

[Sidebar]
American Telemedicine Association
www.atmeda.org
202-223-3333
About 1,300 members. Has a home-care policy committee.

[Sidebar]
National Association for Home Care
www.nahc.org
202-547-7424
Represents about 18,000 home-care agencies.

[Sidebar]
See "Health Technology is Coming Home (And How!) " in The Last Word, page 36.

[Sidebar]
The primary need for today's homecare population is more frequent and convenient monitoring of chronic diseases and conditions, according to a 1998 workshop on future trends in medical device technologies sponsored by the National Science Foundation and the FDA. A wide range of health and social services gradually are being delivered at home to recovering, disabled, chronically ill, or terminally ill people.
Chronically ill infants and children are receiving sophisticated medical treatment in a familiar and secure home environment. Many younger adults who are disabled or recuperating from acute

[Sidebar]
illnesses are choosing home care, whenever possible. Adults and children diagnosed with terminal illnesses also are being cared for at home.
Audrey Kinsella, a medical research librarian who specializes in home health-care product trends and applications, says that the trend toward earlier discharges from acute care settings to home while people still may need daily care also has been driving the home health-care market. "And some see it as a wonderful adjunct to the care they're already getting," she adds.
According to a study conducted by Kaiser Permanente's Medical Care Pro

[Sidebar]
gram, the greatest users of home-health services are older people-also the most rapidly growing segment of the population. Two-thirds of Americans over 62 have at least one chronic disease, and so may need to use home-monitoring devices daily, such as heart rate monitors. Heart disease, diabetes, and respiratory problems are the top chronic diseases of this age group. And more and more older people, electing to live independent, non-institutionalized lives, also are receiving home-care services as their physical capabilities diminish.

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The Washington Post

Online Heart Exams for Veterans:[FINAL Edition]

Leslie Walker. **The Washington Post**. Washington, D.C.:May 18, 2003. p. F.07

Abstract (Summary)

The CareLink Network, created last year by medical device maker Medtronics Inc. (www.medtronic.com/carelink_network) isn't quite Dick Tracy enough to beam patients' vital signs directly to doctors' computers; instead, patients wave special antennas over their implanted heart-monitoring devices to relay data via a telephone connection over the Internet to the CareLink Network.

This new feature (AOL keyword: Instant Greetings) allows subscribers to the online service -- AOL 8.0 is required -- to send multimedia messages to pals on the service. These e-greetings don't appear inside the usual instant-messaging window, though; They dance and writhe all over the recipient's screen, accompanied by 10 to 20 seconds of sound.

Web Watch reported last week that Microsoft said it was developing the "iLoo" as an Internet-connected Porta-Potty in England. But on Monday the Redmond, Wash., giant told reporters it had all been an April Fool's joke -- notwithstanding the April 30 date of the initial announcement. Then at midweek, Microsoft said no, the project had been for real, but was being killed by higher- ups.

Full Text (539 words)

People are used to looking on the Web for medical advice, but a doctor still has to give you a checkup in person. That could be changing. Military veterans with heart conditions can now arrange for online monitoring of their tickers in a new program the Department of Veterans Affairs has begun offering.

The CareLink Network, created last year by medical device maker Medtronics Inc. (www.medtronic.com/carelink_network) isn't quite Dick Tracy enough to beam patients' vital signs directly to doctors' computers; instead, patients wave special antennas over their implanted heart-monitoring devices to relay data via a telephone connection over the Internet to the CareLink Network.

"It's such an advantage for patients, because now they typically have to go to the doctor's office every three months just to do a simple device check," said Medtronics spokeswoman Valerie Lind. "Many of them drive hours to get to their clinic. This will take the place of many of those visits."

CareLink uses a password-protected Web site to let doctors and health workers access patient data. Patients get their own customized Web pages for viewing their vital signs and communicating with their doctors.

Since the Internet heart-monitoring network became commercially available last fall, about 1,200 heart patients have signed up and are being monitored, including some at Washington Hospital Center and a private clinic in Takoma Park. The VA is expected to add 1,500 patients to the network.

So far, the only hardware that supports the network is a few models of implantable cardioverter-defibrillators, which detect and correct fast heart rates and revive people in cases of heart stoppage. But Lind said Medtronics is planning to add more devices soon.

If you thought pop-up ads were obnoxious, wait until you see "AOL Instant Greetings." The only thing these digital ditties seem to have over in-your-face Internet ads is their source -- supposedly your friends.

This new feature (AOL keyword: Instant Greetings) allows subscribers to the online service -- AOL 8.0 is required -- to send multimedia messages to pals on the service. These e-greetings don't appear inside the usual instant-messaging window, though; They dance and writhe all over the recipient's screen, accompanied by 10 to 20 seconds of sound.

To start, AOL is offering 150 different "templates" that include dancing penguins, animated cats and the like, to which users can add their own text greetings. Recipients can block the messages by choosing not to accept them, just as they can with instant messages.

Microsoft Corp. might have gotten decent publicity over a new paid Internet radio service, but instead it found itself drowned in a wave of ridicule over its on-again, off-again Internet toilet.

Web Watch reported last week that Microsoft said it was developing the "iLoo" as an Internet-connected Porta-Potty in England. But on Monday the Redmond, Wash., giant told reporters it had all been an April Fool's joke -- notwithstanding the April 30 date of the initial announcement. Then at midweek, Microsoft said no, the project had been for real, but was being killed by higher- ups.

For the record, MSN Radio Plus offers more than 200 channels of streaming music online, programmed by Microsoft; the $5/month (or $30/year) subscription fee removes the free version's ads.

entertainment.msn.com/station

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New dimensions open up for patients and doctors HEALTH AND MEDICINE by Nuala Moran The internet will transform medical diagnosis and healthcare, while patients will gain access to far more information about their illnesses and possible treatments:[Surveys edition]

Moran, Nuala. **Financial Times**. London (UK):Dec 1, 1999. p. 04

Abstract (Summary)

True patient power could finally be on the way - courtesy of the internet. For just as it is changing the structures and practices of business, the internet has the power to transform health and medicine.

An early indication of the way the balance of power will shift is the phenomenon of the empowered patients - individuals who are already using the internet to become more informed about their condition and the possible treatments for it than are their doctors.

An example is ukpractice, a web portal for medical information. This site is only open to medical practitioners, offering secure access to medical databases, online textbooks, job vacancies and bulletin boards, and enabling drugs and medical devices companies to do direct marketing.

Full Text (924 words)

True patient power could finally be on the way - courtesy of the internet. For just as it is changing the structures and practices of business, the internet has the power to transform health and medicine.

While it is creating a customer-centric business world, the internet will pave the way to patient- or people-focused health care.

An early indication of the way the balance of power will shift is the phenomenon of the empowered patients - individuals who are already using the internet to become more informed about their condition and the possible treatments for it than are their doctors.

This is not only challenging doctors' authority, it is also beginning to drive the market for pharmaceuticals.

Sufferers can find out about new drugs and demand to be prescribed them, often before doctors are fully briefed by the manufacturers.

Indeed, companies in the medical and pharmaceutical market are increasingly using the internet as a marketing tool.

An example is ukpractice, a web portal for medical information. This site is only open to medical practitioners, offering secure access to medical databases, online textbooks, job vacancies and bulletin boards, and enabling drugs and medical devices companies to do direct marketing.

Similarly, in the US, Healtheon.com/WebMD, acts as a healthcare portal for both doctors and ordinary users.

The service links physicians, medical institutions, consumers, laboratories and health insurance companies, allowing the medical profession to streamline inefficient manual and paper-based processes and improve the quality of care.

At the same time the service claims to "allow consumers to take a proactive role in the management of their health care".

The internet is also poised to change Institutional care by creating the "hospital without walls", according to Ian Taylor, chief operating officer of Abovenet, a company which provides broadband Internet services.

In contrast to installing bespoke high capacity networks, installing high capacity internet access will not be very expensive.

Such networks will make it possible to link in elements from outside the hospital such as laboratories, general practitioners, regionally or internationally-based experts and diagnostic equipment.

Improving communications will improve administration, for example ensuring that patient records are complete and on hand, or allowing doctors to make appointments electronically with hospital consultants.

But cheap, secure internet-based communication also has the power to change the practice of medicine.

Building on experiments in telemedicine, it will enable medical experts to be brought together with the best diagnostic equipment and patients.

"Initially, cheap, secure, high bandwidth will be tested on non-medical applications, to build confidence in the techniques, the availability of the network, and in the security," says Mr Taylor.

"What we are able to offer now is clean and scalable bandwidth, which can go anywhere. Whereas before, telemedicine has depended on expensive point-to-point dedicated links, we begin to have the ability to link any-to-any.

"Diagnostics can not only be carried out remotely, but data can be brought in from other sources.

"Experts could be linked by camera, or on e-mail links, to make their contribution to a diagnosis."

The presence of broadband internet links will also make it possible to draw on computing resources beyond the hospital. An example is a radiology service being developed by IBM in collaboration with the University of Amsterdam in the Netherlands.

Two-dimensional magnetic resonance images (MRI) and computer tomography (CT) scans are transmitted by ultra-fast, high capacity internet links to be processed by remote super-computers into 3-D images.

"MRI and CT scans can only record one cross-section at a time, and so lack the depth that is sometimes required for a full diagnosis," says Peter Sloot, one of the developers of the Virtual Radiology Explorer.

"By mounting these cross-sections into an overall 3-D image, the specialist can travel through the human body.

"The body can be studied from all angles, leading to better diagnoses and sparing patients unpleasant diagnostic procedures, such as keyhole surgery and endoscopic examinations."

Such scans could also be used to monitor the rate of growth of cancerous tumours, or to assess if treatment to shrink them is working.

Mr Sloot says it is hoped to develop the system further, so that instead of working from static 3-D images, surgeons could see dynamic simulations. These could be used, for example, to monitor blood flows when planning heart by-pass operations.

In the same way that wireless hand-held devices are forecast to transform business applications, wireless diagnostic devices will be used to measure and transmit patient information.

For example, medical staff dealing with accident victims could have devices for transmitting data to the hospital in advance of the patient.

Phil Meadows, a consultant at Computer Sciences Corporation, says that CSC has an alliance with the mobile phone company Nokia, in which the two are investigating future applications of mobile telecommunications in medicine.

He believes there will be systems for self-diagnosis, for example toothbrushes which monitor pathogens in saliva and warn of potential infections or implants that monitor the blood, checking for changes in hormone or blood

sugar levels.

Each patient would have a baseline check to characterise his or her "normal" state of health. The monitoring systems would then look for exceptions.

Data would be transmitted from the wireless devices or implants to doctor's surgeries, where computer-based expert systems would suggest appropriate treatments for patients and automatically generate a prescription.

"We have become used to centralisation of health services in order to cut costs and support specialisms," says Mr Taylor of Abovenet. "With better, cheap internet-based communication, there can be a move back to more community-based medicine."

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Telemedicine: An emerging health care technology

Mary B Myers. **The Health Care Manager**. Frederick:Jul-Sep 2003. Vol. 22, Iss. 3, p. 219-223

Abstract (Summary)
Telemedicine uses advanced telecommunication technologies to exchange health information and provide health care services across geographic, time, social, and cultural barriers. All telemedicine applications require the use of the electronic transfer of information. Telemedicine encompasses computer technologies using narrow and high bandwidths for specific types of information transmission, broadcast video, compressed video, full motion video, and even virtual reality. There are many types of common medical devices that have been adapted for use with telemedicine technology, and many clinical services can be provided via telemedicine to patients who live in physician shortage areas. The greatest challenges for telemedicine in the twenty-first century are financing, safety standards, security, and infrastructure. [PUBLICATION ABSTRACT]

Full Text (2568 words)

[Headnote]
Telemedicine uses advanced telecommunication technologies to exchange health information and provide health care services across geographic, time, social, and cultural barriers. All telemedicine applications require the use of the

electronic transfer of information. Telemedicine encompasses computer technologies using narrow and high bandwidths for specific types of information transmission, broadcast video, compressed video, full motion video, and even virtual reality. There are many types of common medical devices that have been adapted for use with telemedicine technology, and many clinical services can be provided via telemedicine to patients who live in physician shortage areas. The greatest challenges for telemedicine in the twenty-first century are financing, safety standards, security, and infrastructure. Key words: store and forward, telemedicine, video teleconferencing

THIS ARTICLE IS NOT intended as a technical report on the required telecommunications technology for telemedicine. The purpose of this project is to provide a basic overview of the history, current applications, and future challenges for telemedicine as a part of twenty-first century health care.

Before telemedicine can be discussed, it must be defined. According to Reid, telemedicine is the use of advanced telecommunications technologies to exchange health information and provide health care services across geographic, time, social and cultural barriers.1(p. 10) All the advanced telecommunication technologies noted in this report have one major convergence of commonality: telemedicine applications require the use of electronic transfer of information. This transfer may occur in different ways depending on application and equipment.

When considering information transfer and telemedicine, technologies such as the telephone and fax machine must not be over-looked. Long before videoconferencing or Picture Archiving and Communications Systems (PACS) existed, health care clinicians communicated and transferred medical information via telephone. With the advent of the fax machine, written information was transferred electronically via standard telephone line. Today, telemedicine encompasses computer technologies using narrow and high bandwidths for specific types of information transmission, broadcast video, compressed video, full motion video, and even virtual reality. Several clinical applications utilizing these technologies will be discussed later this article.

HISTORY OF TELEMEDICINE

Before proceeding further, a brief history of telemedicine is in order. What is considered telemedicine by health care clinicians today had its start in the late 1950s. There is even evidence that suggests the concepts dates back to 1924.1(p. 14) The April 1924 issue of Radio News Magazine featured a drawing of a physician viewing his patient over the radio, which included a television screen and an RCA Victor horn-shaped speaker. Widespread use of TV was decades away. The first acknowledged cross-state demonstration of telemedicine occurred at the 1951 New York World's Fair. Dr. Albert Jutras of Montreal, Canada, started Teleradiology in 1957. By 1959 a tele-education and telepsychiatry program "was implemented at the Nebraska Psychiatric Institute by Dr. Cecil Wittson.

But over the last three decades, the utilization and expansion of telemedicine has waxed and waned. The primary reason for this is lack of funding. For the most part, the rapid advances in telecommunication technology were matching the pace of potential applications. Patients and clinicians were also satisfied with the outcomes of telemedicine encounters. However, as grant opportunities became scarce, programs were forced to cease operations and it became evident that for telemedicine programs to continue, they must become self-sustainable. The financial challenges to telemedicine will be discussed later in this report.

The U.S. Army must be mentioned at this point in the discussion for its part in the history of telemedicine. The army has pioneered telemedicine, and many of the advances of the technology today are a direct outcome of work done by the military. Over the last 100 years, many advances in science and medical care have come courtesy of the U.S. military. For obvious reasons, the army was quite interested in developing technology that would facilitate providing health care to soldiers on the front or based in remote areas. More than one-third of the presentations offered at the 7th Annual American Telemedicine Association meeting held June 2002, were authored by U.S. military officers and Veterans Administration staff. Military personnel from several European countries also made presentations.

TELEMEDICINE TECHNOLOGY

There are two primary forms of telemedicine technology in use today. These two technologies support the majority or rural, home, school, and prison telemedicine programs.

The first type of telemedicine technology is video teleconferencing. This type of technology is not limited to health care. In fact, most major corporations utilize video teleconferencing for day-to-day operations. The use of this

technology lends itself to real-time patient consultations and distance learning. In the patient consultation, the patient and assisting clinician at the remote site connect with a clinical specialist at an office or urban center via video link. Using cameras and microphones at both sites, the clinical specialist can interview and examine the patient. There are also adjunctive tools that can assist the clinical specialist in the exam. Examples of these are the electronic stethoscope that can be used to assess breath and heart sounds remotely, electronic otoscope for remote examinations of the ear, and a high-resolution general exam camera to inspect skin lesions. This list is far from inclusive, as there is an emerging industry devoted to the development of medical devices to support telemedicine. A real-time demonstration of an evaluation of a stroke patient was presented at the 7th Annual American Telemedicine Association meeting in June 2002. With equipment set up in the Los Angeles Convention Center, an army neurologist was able to demonstrate a comprehensive stroke evaluation on a mock patient located at the Walter Reed Army Hospital in Maryland. This was an exciting example of the potential for real-time evaluation of a patient in the acute care setting. In addition to the assessment of patients, video teleconferencing can be used for case reviews, health care professional continuing education, and community health care education.

The second type of telemedicine technology is referred to as "store and forward." This refers to transferring digital images from one location to another. Examples of this have been previously mentioned. An image is taken using a digital camera, or in the case of CT scans the images will already be digitized. The information is then sent to a remote location for review. This method is commonly used in non-emergency situations when the situation does not require immediate diagnosis or results.

CURRENT TELEMEDICINE APPLICATIONS

As telecommunication technology explodes, the applications to health care are keeping up with the explosion. In the 1990s, the most common telemedicine applications involved teleradiology and two-way videoconferencing. In teleradiology, digitized X-ray images are transmitted to a remote site for review by a radiologist. Teleradiology is an example of what telemedicine can do across medical disciplines. Through teleradiology, the expertise of a radiologist may be brought to an area where there may be critical shortages of radiologists. In 2002, many clinical applications are being supported and facilitated by telemedicine. Patients in remote locations may no longer be at a disadvantage because they live in areas with a physician shortage. Telemedicine supports both diagnostic and evaluative care for patients and the clinicians who care for them. There are specific areas of the country where physicians are in demand. In many primarily rural areas, there are just not enough physicians to meet the needs of the population. These areas are designated by the federal government as health professional shortage areas (HPSAs). Nonphysician extenders such as physician assistants and nurse practitioners are often the sole health care providers for rural populations. Telemedicine brings the services of physician specialists to these areas.

In addition to teleradiology, other diagnostic and evaluative applications include telepathology,2 telecolposcopy, teledermatology,3 neuropsychiatric and stroke evaluation via real-time two-way videoconferencing. This list is not inclusive, as new applications are constantly being introduced. Most of these applications are occurring at a primary care practice site with consultation with an office-based or hospital-based specialist. In the instance of stroke evaluation, consultations are originating in a remote emergency department, and the consultant may be evaluating the patient from a large urban medical center. This type of application is exciting because in the instance of stroke, early intervention can significantly improve outcomes. Patients can receive appropriate treatment in their own community without the need to travel many miles to an urban center. But these applications focus primarily on episodic health care.

Telemedicine applications have found a place in home care, and remote monitoring appears to be a useful adjunct in the ongoing care of patients, particularly the elderly.4(p.33) Much work has been accomplished in the area of remote home monitoring by the Veterans Administration (VA).5 Telehome care may be the leading application of telemedicine due to an aging population, the pending nursing shortage, and Medicare reimbursement, according to Jay Sanders, MD, president and CEO of the Global Telemedicine Group and senior editor of the Telemedicine and e-Health Journal. The VA's Florida/Puerto Rico Veterans Integrated Service Network (VISN-8) provides home care to approximately 1,200 patients in Florida, Puerto Rico, and southern Georgia. The care to this population is coordinated by 23 clinicians and is supported by remote home monitoring that is achieved via POTS (plain old telephone service). Data from this project suggest that remote home monitoring has reduced the outpatient, emergency department, and inpatient hospital admissions within the network.6 Home monitoring is also well received by patients and compliance is high even among elderly populations.7

CHALLENGES TO TELEMEDICINE IN THE TWENTY-FIRST CENTURY

The issues surrounding telemedicine today are primarily financial in nature. Start-up costs can be significant due to equipment costs, and the current reimbursement climate may not provide an adequate return on investment.6 According to Dena Puskin, director of the Office for the Advancement of Telehealth, Health Resources and Services (HRSA), the lack of money has driven decision making relative to telemedicine.8 Since the advent in the mid-1980s of diagnostic related groups (DRGs) and prospective payment procedures for Medicare patients, the precedent has been set for all third-party payers to move from cost-based reimbursement to prospective reimbursement. Until recently, most payers did not cover telemedicine and telehealth services. But there were some exceptions to this practice. Services that did not require face-to-face interactions, such as EKG interpretation and teleradiology, have been reimbursed. In 1997, the Balanced Budget Act included a small change in the Medicare payment structure that positively impacted the future of reimbursement for telemedicine services. In December 2000, Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement Act of 2000, which went into effect October 1, 2001.9 This act eliminated the presenter and fee-sharing requirements, expanded eligible locations to HPSAs and counties not part of a metropolitan statistical area, increased the number of current procedural terminology codes that are reimbursable by Medicare, and provided full reimbursement to specialists providing telemedicine consultations. In addition to Medicare reimbursement, currently 20 states have state Medicaid programs that pay for specific telemedicine services. Some private insurers also provide limited coverage. However, there is still resistance by payers to reimburse telemedicine services on the same level as face-to-face services.10

The 2001 Telemedicine Report to Congress identifies four other key issues that will impact the use of telemedicine in the 21st century.9 The primary legal issue relevant to telemedicine is cross-state licensure. To date, 26 states have laws that regulate out-of-state practitioners; 21 of those states require that a physician have full licensure to practice in states where patients are located. Nursing has taken a somewhat more lenient approach to the cross-state licensure issue. To date, 12 states have adopted the Interstate Nurses Licensure Compact that is based on mutual recognition of state nursing licensing boards.

The next issue of concern is safety standards throughout all facets of health care. Technical standards will facilitate interConnectivity and interoperatibility between sites. Without such standards in place, development of telemedicine networks will be hampered. Clinical protocols and standards are also necessary to provide safe, effective care. The Joint Commission on Accreditation of Healthcare Organizations has included basic language addressing telemedicine standards. Inclusive standards were clarified in January 2003 and will be implemented January 1, 2004. Other agencies, such as the Food and Drug Administration, the Federal Trade Commission, and the Center for Devices and Radiologic Health, are also involved with overseeing the safety and effectiveness of telemedicine devices and computer software.

The third issue is that of confidentiality and security of electronic transmission of medical information. With the introduction of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), standards have been mandated that govern electronic data exchange, protect the privacy of identifiable health information, and secure electronic signatures; this list is not inclusive but highlights major areas. With HIPAA, the challenge for telemedicine providers will be dealing with multiple state privacy provisions and the overriding federal provisions, which may be in conflict. Currently, a study is being conducted by the Office for the Advancement of Telehealth to identify the privacy issues unique to telemedicine and to interpret HIPAA privacy rules as they apply to telemedicine practice.

The last issue is that of infrastructure. The cost of maintaining telemedicine infrastructure remains the greatest expense to those organizations promoting and developing telehealth programs. The Telecommunications Act of 1996 made the Federal Communications Commission accountable for the Universal Service Program. This program provides rural health care providers with discounts on telecommunication charges. In addition, other federal monies have been appropriated to assist rural programs with the expense of maintaining the telemedicine infrastructure.

Two key trends that will impact the delivery of health care via telemedicine are the rapidly changing technology and the aging population. These trends point to the rapid growth of telehomecare. Issues of access to care in urban and rural environments and reimbursement will be paramount and will drive policy-making decisions. If telehomecare can be proven to be cost effective, third-party payers will be influential in these decisions and may determine the fate of future telemedicine initiatives in the United States.

[Sidebar]
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[Sidebar]
As telecommunication technology explodes, the applications to health care are keeping up with the explosion.

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Telemedicine; New Internet protocol used successfully for ultra- telephonic stethoscope

Medical Devices & Surgical Technology Week. Atlanta:Nov 10, 2002. p. 7

Abstract (Summary)
ATI developed IP connectivity in response to the increasing use of IP networking in videoconferencing

technologies. The IP software allows the CareTone Ultra to run independently yet alongside video or data streams. The CareTone Ultra, which transmits high quality heart and lung sounds, is recognized as the premium tele- stethoscope, and is used widely in institutional telemedicine programs throughout the world, as well as in ATI's home telehealth system.

Full Text (440 words)

American TeleCare, Inc. (ATI) announced the successful development and market introduction of a software program for transporting CareTone Ultra Digital Tele-Stethoscope signal over IP (Internet protocol) networks.

The development was facilitated by invaluable feedback and testing from the University of Texas Medical Branch at Galveston (UTMB), one of the largest users of CareTone Ultra.

ATI developed IP connectivity in response to the increasing use of IP networking in videoconferencing technologies. The IP software allows the CareTone Ultra to run independently yet alongside video or data streams. The CareTone Ultra, which transmits high quality heart and lung sounds, is recognized as the premium tele- stethoscope, and is used widely in institutional telemedicine programs throughout the world, as well as in ATI's home telehealth system.

UTMB has the most extensive telemedicine network in the U.S., currently conducting over 500 remote consultations weekly. They utilize 75 CareTone Ultras within the corrections component to their telemedicine services. The corrections program provides offenders in the state's penal system with access to healthcare services. Telemedicine allowed for timely patient evaluations and interventions, which has resulted in a $650 million cost savings over a 6-year period.

Says Dr. Glenn Hammack, director of health informatics and telemedicine for UTMB Correctional Managed Care, "The CareTone Ultra tele-stethoscope is an integral part of our Digital Medical Services telemedicine system. It provides the high quality real-time heart and lung sounds we require for primary care and cardiology services, better than other tele-stethoscopes we evaluated. We have been very pleased with ATI's responsiveness to our need for an IP protocol for the stethoscope, and we were pleased to provide the requirements for the development of this new technology."

"ATI is committed to maintaining the integrity of the interface between the patient and provider," says Randall Moore, MD, MBA, chief executive officer for American TeleCare. "The tele- stethescope enables the clinician to perform many parts of the physical examination that would otherwise require the patient and clinician to be present in the same physical location."

American TeleCare, Inc., is a telehealth solutions company. The CareTone Ultra line of tele-stethoscopes started in 1995, and includes an analog model and a low bandwidth digital model plus the software for the IP transport. The company currently markets the CareTone Ultras and the AVIVA System, an FDA-cleared telemedicine monitoring system that incorporates live audio/video with integrated electronic medical peripherals to allow a doctor or nurse to conduct remote assessments of patients in their homes. The products are simple to use, and operate through a standard telephone line, the company says.

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